VOL. 8 NO. 2 JULY 2015

PRO TE: SOLUTIO

SOLUTIONS FOR YOU

STORM CLOUDS GATHER:
An FDA Proposal to Eliminate Generic Preemption

LAW ELEVATED

BUTLER | SNOW

butlersnow.com

DEAR CLIENT

CHRISTY D. JONES
Co-Chair
Litigation

CHARLES F. JOHNSON
Co-Chair
Business and Corporate Healthcare

Summer is in full swing and certain topics are (staying) hot—especially regulatory issues, from new proposed rules to challenges to case law to strategic considerations.

Generic preemption remains a hot topic. In *Storm Clouds Gather: An FDA Proposal to Eliminate Generic Preemption*, we explore the FDA's proposed rule that is designed to address challenges related to product safety labeling. Given the FDA's plan to have a new rule finalized by September 2015, we offer an early look at what the rule could be and its potential impact.

Another issue that device manufacturers are steaming about is the claim that FDA clearance of a device is not relevant to safety and effectiveness. What is mere dictum from *Medtronic v. Lohr* has led to arguments by the plaintiffs' bar that the 510(k) clearance process essentially amounts to *no* safety review of those devices by the FDA. This ignores the importance of device classification, an essential part of the clearance process, which depends entirely on an FDA assessment of safety and effectiveness. To explain this conflict, *Classification: When "Equivalence" Means "Safety,"* analyzes the classification of surgical mesh and explains how it provides assurances of safety that apply to all "equivalent" devices.

Our final article also touches on all things regulatory. In *Thinking Bigger: Broadening Regulatory Strategy For New Medical Devices By Planning For Both Regulatory And Reimbursement Approval*, we evaluate strategies that medical device developers may consider in order to keep from getting singed. These include efforts to meet the demands of the ever-changing health economy, including how to enhance reimbursement likelihood for new medical technologies.

We hope that this information offers some insight into areas that are of interest to you.

TABLE OF CONTENTS

STORM CLOUDS GATHER:

AN FDA PROPOSAL TO ELIMINATE GENERIC PREEMPTION

On March 18, 1925, the deadliest tornado in recorded history struck the United States. Later named the Tri-State Tornado, this merciless twister tore through parts of Missouri, Illinois and Indiana for over three hours. Traveling at speeds in excess of 70 miles per hour, the tornado carved a path of destruction 219 miles long and killed 695 people. In addition to the mass casualties, thousands of structures and entire towns were destroyed by the tornado's mile-wide path. In the 90 years since, the world has yet to see a tornado match its power and wrath.[1]

Meteorological experts say the Tri-State Tornado's extreme devastation was partly attributable to many residents' mistaken belief that the brooding clouds were nothing more than a thunderstorm.[2] Much like that day in 1925, ominous storm clouds have begun to gather around a new proposal from the Food and Drug Administration (FDA) designed to eliminate federal preemption of state law failure-to-warn claims against generic drug manufacturers. If approved, the proposed rule could have its own devastating consequences by jeopardizing public safety, driving up the cost of generic drugs and increasing product liability litigation for manufacturers. With the public hearing and comment period for the rule now complete, the arguments for and against the proposal are clear. However, one question remains: Is this the end of generic preemption?

If approved, the proposed rule could have its own devastating consequences by jeopardizing public safety, driving up the cost of generic drugs and increasing product liability litigation for manufacturers.

BACKGROUND

The United States Supreme Court has recently considered federal preemption questions involving state law failure-to-warn claims in two landmark cases. In Wyeth v. Levine in 2009, the Supreme Court held that federal law did not preempt a state law tort claim against a brand-name drug manufacturer for inadequate warnings on their product labeling.[3] According to the Court, because the brand-name manufacturer could have unilaterally strengthened the warnings on its product labeling through the "changes being effected" (CBE) process, it was possible for the manufacturer to comply with both federal and state requirements.[4]

Two years later, in Pilva v. Mensing, the Court found that a failure-to-warn claim against a generic manufacturer was preempted.[5] There, the Court reasoned that because the generic manufacturer was not permitted to unilaterally strengthen its warning label through the CBE process or by the use of "Dear Doctor" letters, it was impossible for the generic drug manufacturer to comply with both state and federal law.[6]

As a result of the Court's decisions, a consumer who takes a brand-name drug can sue the manufacturer for inadequate warnings, while one who takes the generic version of the drug cannot.[7] Although all nine justices on the Supreme Court agree that this outcome "makes little sense,"[8] the majority of the Court says it is not the role of the judiciary to "decide whether the statutory scheme established by Congress is unusual or even bizarre," and that "Congress and the FDA retain the authority to change the law and regulations if they so desire."[9]

FDA'S PROPOSED RULE

Following the *Mensing* decision, the consumer rights advocacy group Public Citizen petitioned the FDA to amend its regulations to allow generic drug manufacturers to revise their product labeling through the CBE and prior-approval supplement procedures.[10] In November 2013, the FDA granted that request and proposed a new rule that would allow generic manufacturers to unilaterally update safety labeling to consumers before FDA approval.[11] If finalized, the rule will effectively nullify the Supreme Court's decision in *Mensing* and eliminate preemption of failure-to-warn claims against generic drug manufacturers.[12]

Under the FDA's proposed rule, a generic drug manufacturer would be able to add or strengthen a warning on its product label by submitting to the FDA a CBE supplement – the same process currently used by brand manufacturers.[13] This process would begin when a manufacturer receives certain types of "newly acquired information"[14] related to drug safety.[15] Once in receipt of new information, the generic manufacturer would submit a CBE supplement to the FDA requesting a proposed change to its labeling.[16] At the same time the supplement is submitted to the FDA, the generic manufacturer would also send notice of the proposed labeling change, along with a copy of the information supporting the change, to the new drug application holder of the listed drug, commonly known

> As a result of the Court's decisions, a consumer who takes a brand-name drug can sue the manufacturer for inadequate warnings, while one who takes the generic version of the drug cannot.

as the brand-name manufacturer.[17] This process will ensure that the brand-name manufacturer is promptly advised of the new safety information.[18] Upon submission of a CBE supplement to the FDA, the generic manufacturer could distribute the revised safety labeling to the public, resulting in at least temporary differences in safety-related labeling between brand-name and generic drugs.[19] While such differences are currently prohibited by law, the proposed rule would create an exception for generic drug labeling that is temporarily inconsistent with its brand-name counterpart due to safety-related labeling changes submitted via the CBE supplement process.[20]

Once the FDA receives the CBE supplement from the generic manufacturer, the Agency would conduct a review of the proposed labeling changes and determine whether the label update is justified.[21] During this review, the FDA would consider submissions by both the brand-name and generic manufacturers.[22] Any proposed changes during this time would be publicly available via a dedicated webpage, and interested parties could subscribe to a free e-mail service to receive updates.[23]

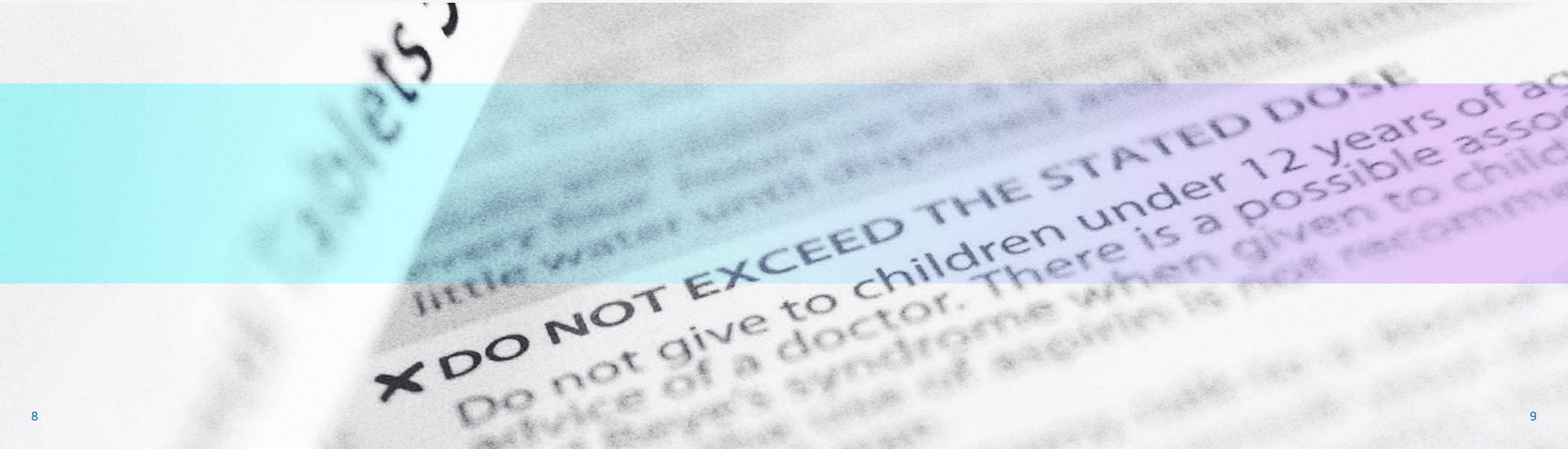
After reviewing the CBE supplement, the FDA could approve, disapprove, or request modifications to the proposed labeling changes.[24] The FDA would approve the proposed changes only if such changes would also be approved for the brand manufacturer.[25] This process will ensure that the approved labeling for brand-name and generic drugs remains the same.[26] Upon FDA approval, all generic manufacturers would be required to submit a CBE supplement with conforming labeling changes within 30 days.[27] If a generic drug manufacturer fails to update its label, the FDA may take steps to withdraw the product from the market.[28]

CURRENT PRACTICE

The proposed rule is a departure from current practice, which allows only brand-name manufacturers to utilize the CBE supplement process to update their labeling.[29] Because a generic drug is required to have the same labeling as its brand-name counterpart, generic manufacturers must currently wait to make safety-related labeling changes until the brand-name manufacturer has received FDA approval to update its own safety information.[30] The proposed rule would, therefore, "create parity" between brand and generic manufacturers "with respect to submission of CBE supplements for safety-related labeling changes" and facilitate the prompt communication of critical drug safety information to prescribers and the public.[31]

ARGUMENTS FOR AND AGAINST

Supporters of the FDA's proposal argue that the rule will improve patient safety, hold generic manufacturers legally accountable for inadequate warnings and incentivize robust pharmacovigilance.[32] With generic drugs accounting for an estimated 86% of all dispensed medications,[33] supporters argue that generic manufacturers should be allowed to unilaterally update safety-related product labeling to ensure that patients and prescribers have the most current information.[34] Moreover, by eliminating generic preemption in failure-to-warn claims, the proposed rule would restore the ability of consumers to recover for injuries caused by inadequate warnings and ensure that generic manufacturers pay their fair share.[35] Finally, with no generic preemption, the proposed rule will



incentivize manufacturers to fund and support extensive post-marketing surveillance.[36]

While the FDA's proposed rule has received support from many consumer advocacy groups, the proposal has not been without critics. Since its release, the proposed rule has come under fire by generic and brand-name manufacturers, as well as some members of Congress.[37] Critics of the proposed rule argue that differing labels in the market will create confusion among doctors and consumers, jeopardizing patient safety and undermining public confidence in generic drugs.[38] If passed, the proposal will also result in additional tort liability for manufacturers and healthcare providers, driving up the cost of generic drugs.[39] Finally, critics contend that the proposed rule is unlawful under the 1984 Hatch-Waxman Act because it would allow for temporary differences in labeling between generic and brand-name drugs, undermining the law's "sameness" requirement.[40]

ECONOMIC IMPACT

The FDA states that the proposed rule will "generate little cost," estimating the net increase to be between $4,237 and $25,852 per year.[41] The FDA's cursory economic assessment, however, focuses primarily on the cost manufacturers will incur in submitting and reviewing CBE supplements, and ignores the expected increase in product liability litigation.[42] It also gives no consideration to factors like higher insurance premiums, manufacturers who may exit or decline to enter the market for products carrying increased liability risk, insurance companies who may leave the market when faced with insuring against greater risk, or generic manufacturers who may have to bear the cost of duplicating brand companies' efforts to monitor for safety-related issues.[43]

In response to the FDA's cost analysis, the Generic Pharmaceutical Association (GPhA) commissioned economist and policy advisor Alex Brill to perform a separate economic assessment of the FDA's proposed rule.[44] In contrast to the FDA's projections, Brill estimates that new product liability risks arising from the proposed rule could "increase spending on generic drugs by $4 billion per year."[45] According to Brill, these additional costs will be passed on to consumers, causing the price of generic drugs to increase and forcing manufacturers out of the market.[46] While Brill's assessment has already been criticized as "fundamentally mistaken" by an economist sponsored by the American Association for Justice (formerly the Association of Trial Lawyers of America),[47] both sides agree that the proposed rule will generate additional costs for generic manufacturers. The critical question, then, is how much?

INFLUENCE OF PLAINTIFFS' BAR

Given the potential tort liability that would result if the rule is finalized, it is no surprise that the FDA's proposal has received strong support from plaintiff attorneys.[48] In fact, the involvement of plaintiff attorneys in the development of the proposed rule has been so pronounced that some members of Congress have expressed "significant questions" about the FDA's "primary motivation" for the proposal.[49] Members of Congress have also suggested that FDA Commissioner Margaret Hamburg was less than truthful with them when she testified in front of a House Appropriations Subcommittee meeting in March of 2014 the FDA had met with the generic drug industry during development of the proposed rule.[50] In truth, the only outside interest group the FDA had consulted with at the time was the American Association of Justice.[51]

After coming under fire from Congress, the FDA held a public meeting on March 27, 2015 to "promote transparency" and receive input on the proposed rule.[52] Present at the meeting were FDA personnel, individual stakeholders, consumer advocates, attorneys, pharmaceutical manufacturers and others.[53] Four plaintiff attorneys and nine individuals sponsored by the American Association for Justice were among the speakers who provided comments in support of the FDA's proposal.[54] A central theme of the commentary was holding generic manufacturers legally accountable for inadequate warnings.[55] Representatives from the pharmaceutical industry were also present at the meeting and voiced their opposition to the proposed rule.[56] They and others against the proposal expressed concerns about the rule and urged FDA officials to consider adopting an alternative proposal.[57]

EXPEDITED AGENCY REVIEW: AN ALTERNATIVE PROPOSAL

In response to the FDA's proposed rule, the GPhA and Pharmaceutical Research and Manufacturers of America (PhRMA) teamed up and created an alternative proposal known as the Expedited Agency Review (EAR).[58] The EAR proposal, which would apply to both brand-name and generic manufacturers, would replace the CBE process for safety-related labeling changes with an FDA-led system.[59] The proposal is intended to accomplish the FDA's basic goal of ensuring that manufacturers diligently report and publish important safety information, while avoiding any conflict with Hatch-Waxman's "sameness" requirement.[60]

Under this alternative proposal, an expedited review may be initiated by a brand or generic manufacturer, or by the FDA.[61] Once initiated, the FDA would review all available safety data and engage all manufacturers in a discussion regarding the potential label change.[62] If the FDA determines that a label change is required after reviewing all available safety data, the FDA will inform the brand and generic manufacturers of the content of the final labeling within 15 days, and instruct the manufacturers to update their labeling within 30 days through e-labeling.[63] By using e-labeling, a process whereby manufacturers can distribute updated information electronically instead of in paper form, users will be provided with immediate access to the latest safety information.[64]

Supporters of the FDA's proposal argue that the rule will improve patient safety, hold generic manufacturers legally accountable for inadequate warnings and incentivize robust pharmacovigilance.

JUSTIFICATION FOR THE EAR

According to its creators, the EAR proposal is premised on the belief that manufacturers are "poorly situated" to recommend safety changes in product labeling because they each comprise only a small share of the market, and no manufacturer has access to all available data.[65] In contrast, the FDA "possesses all the significant clinical trial data on a pharmaceutical product and all the adverse event and periodic reports from all manufacturers," and is the "primary repository of safety information for pharmaceutical products through creation of the Sentinel System," the FDA's national electronic system used to track the safety of marketed drugs.[66]

Critics to the EAR proposal disagree and argue that manufacturers, not the FDA, are best situated to track and evaluate safety information.[67] As noted by the Supreme Court in Wyeth, the FDA "has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."[68] Additionally, the adequacy of the drug label is ultimately the responsibility of the manufacturer.[69]

Critics further argue that the EAR proposal is simply an attempt by generic manufacturers to minimize their responsibility for postmarketing vigilance and expand immunity in product liability cases to brand-name manufacturers.[70] By replacing the CBE process with FDA oversight, the EAR proposal essentially "embed[s] a preemption argument in the regulations."[71] If adopted, critics predict that both brand-name and generic manufacturers will argue they are immune from liability for failure-to-warn claims because they are unable to unilaterally update their safety labels and instead require FDA preapproval.[72]

AWAITING FDA ACTION

With the public hearing and comment period complete, generic manufacturers must now await the FDA's final decision. The FDA hopes to have a rule finalized by September 2015[73] and has already indicated that the final rule "may differ" from the current proposal.[74] Despite the best efforts of drug manufacturers, it is unlikely that the EAR proposal will be adopted given that it fails to extend tort-liability to generic manufacturers and imposes greater drug-labeling responsibility on the FDA – two outcomes in conflict with the current proposal.

In the event the FDA approves the rule in its current form, generic manufacturers will likely see an increase in product liability litigation, potentially higher insurance premiums, and additional regulatory requirements. While it is hard to say if the oncoming storm will bring a rain shower or a record-setting tornado, we do know that change is likely to come. Until that time, the question remains: Is this the end of generic preemption? ■

1. John W. Wilson & Stanley A. Changnon, Jr., Illinois Tornadoes 32-38 (Illinois State Water Survey 1971).
2. *Id.*
3. *Wyeth v. Levine*, 555 U.S. 555 (2009)
4. *Id. at 573.*
5. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011)
6. *Id.* at 2575-78.
7. *Id.* at 2581.
8. Id. at 2581, 2583.
9. *Id.* at 2582.
10. Letter from Sidney M. Wolfe, M.D., Dir., Pub. Citizen Health Research Grp., et al., to Div. of Dockets Mgmt., U.S. Food and Drug Admin. (Aug. 29, 2011).
11. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods., 78 Fed. Reg. 67985 (proposed Nov. 13, 2013)(to be codified at 21 C.F.R. pts. 314 and 601).
12. *Id.* at 67989.
13. *Id.* at 67987, 67989.
14. Per 21 C.F.R § 314.3, "newly acquired information" is not just new data, but also includes "new analyses of previously submitted data." *Id.*
15. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods., 78 Fed. Reg. at 67989.
16. *Id.*
17. *Id.* at 67986.
18. *Id.*
19. *Id.* at 67989.
20. *Id.* at 67994-95.
21. *Id.* at 67994.
22. *Id.*
23. *Id.*
24. *Id.* at 67994.
25. *Id.* at 67994.
26. *Id.*
27. *Id.* at 67993.
28. *Id.* at 67986.
29. *Id.* at 67987-88.
30. *Id.* at 67988.
31. *Id.* at 67986, 67989.
32. Letter from Sidney M. Wolfe, M.D., Dir., Pub. Citizen Health Research Grp., et al., to Div. of Dockets Mgmt., U.S. Food and Drug Admin. (Aug. 20, 2011).
33. Transcript of Public Meeting at 34, U.S. Food & Drug Admin., Center for Drug Evaluation & Research Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods. (Mar. 27, 2015), *available* at http://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0112&attachmentNumber=1&disposition=attachment&contentType=pdf.
34. Letter from Sidney M. Wolfe, M.D., Dir., Pub. Citizen Health Research Grp., et al., to Div. of Dockets Mgmt., U.S. Food and Drug Admin. (Aug. 20, 2011).
35. *Id.*
36. *Id.*
37. Letter from Rep. Fred Upton, Chairman, H. Comm. on Energy & Comm., et al., to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin (Jan. 22, 2014); Letter from Ralph G. Neas, President & CEO, Generic Pharm. Ass'n, to Div. of Dockets Mgmt., M.D., U.S. Food & Drug Admin. (Mar. 13, 2014)
38. Letter from Rep. Fred Upton, Chairman, H. Comm. on Energy & Comm., et al., to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin (Jan. 22, 2014)
39. *Id.*
40. *Id.*
41. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods., 78 Fed. Reg. at 67996.
42. *Id.*
43. Alex Brill, FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment 1, 3-5 (2014), *available* at http://www.gphaonline.org/media/cms/Economic_Impact_Study_FDA_Labeling_Rule_-_MGA.pdf.
44. *Id.* at 1, 12.
45. *Id.* at 1.
46. *Id.* at 6.
47. Transcript of Public Meeting at 219, U.S. Food & Drug Admin., Center for Drug Evaluation & Research Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods. (Mar. 27, 2015), available at http://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0112&attachmentNumber=1&disposition=attachment&contentType=pdf.
48. *Id.* at 55-57, 254-65, 276-78.
49. Letter from Rep. Fred Upton, Chairman, H. Comm. on Energy & Comm., et al., to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin (Apr. 22, 2014).
50. *Id.*
51. *Id.*
52. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods.; Public Meeting; Request for Comments; Reopening of the Comment Period, 80 Fed. Reg. 8577 (proposed Feb. 18, 2015)(to be codified at 21 C.F.R. pts. 314 and 601).
53. Transcript of Public Meeting at 2-12, U.S. Food & Drug Admin., Center for Drug Evaluation & Research Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods. (Mar. 27, 2015), *available* at http://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0112&attachmentNumber=1&disposition=attachment&contentType=pdf.
54. *Id.* at 34-55, 58-64, 218-25, 246-54, 265-274.
55. *Id.*
56. *Id.* at 108-39, 142-202.
57. *Id.* at 64-72, 108-39, 142-202, 208-18.
58. Letter from Ralph G. Neas, President & CEO, Generic Pharm. Ass'n, et al., to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin. (Nov. 14, 2014).
59. *Id.*
60. *Id.*
61. *Id.*
62. *Id.*
63. *Id.*
64. Elec. Distribution of Prescribing Info. for Human Prescription Drugs, Including Biological Prods., 79 Fed. Reg. 75506 (proposed Dec. 18, 2014)(to be codified at 21 C.F.R. pts. 201, 606 and 610). The FDA has already endorsed the use of e-labeling under limited circumstances. On December 18, 2014, the FDA proposed a new rule to amend its "labeling regulations to require the electronic distribution of the prescribing information intended for healthcare professionals, which is currently distributed in paper form on or within the package from which a prescription drug or biological product is dispensed." The rule would "not apply to patient labeling (including patient inserts and Medication Guides), or to prescribing information accompanying promotional labeling, which would continue to be provided in paper." Id. at 75506-07.
65. Letter from Ralph G. Neas, President & CEO, Generic Pharm. Ass'n, et al., to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin. (Nov. 14, 2014).
66. *Id.*
67. Letter from Sidney M. Wolfe, M.D., Dir., Pub. Citizen Health Research Grp., et al., to Div. of Dockets Mgmt., U.S. Food and Drug Admin. (Aug. 29, 2011).
68. Wyeth, 555 U.S. at 579.
69. *Id.* at 570-571.
70. Jeff Overley, Critics Rip Big Pharma Alternative To FDA Warning Label Plan, Law360 (Apr. 29, 2015, 3:45 PM ET), http://www.law360.com/articles/648724/critics-rip-big-pharma-alternative-to-fda-warning-label-plan
71. *Id.*
72. *Id.*
73. *Supplement Applications Proposing Labeling Changes for Approved Drugs and Biological Prods.*, Federal Register, https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products (last visited May 16, 2015).
74. Transcript of Public Meeting at 33, U.S. Food & Drug Admin., Center for Drug Evaluation & Research Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Prods. (Mar. 27, 2015), *available* at http://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0112&attachmentNumber=1&disposition=attachment&contentType=pdf.

By Josh Hill

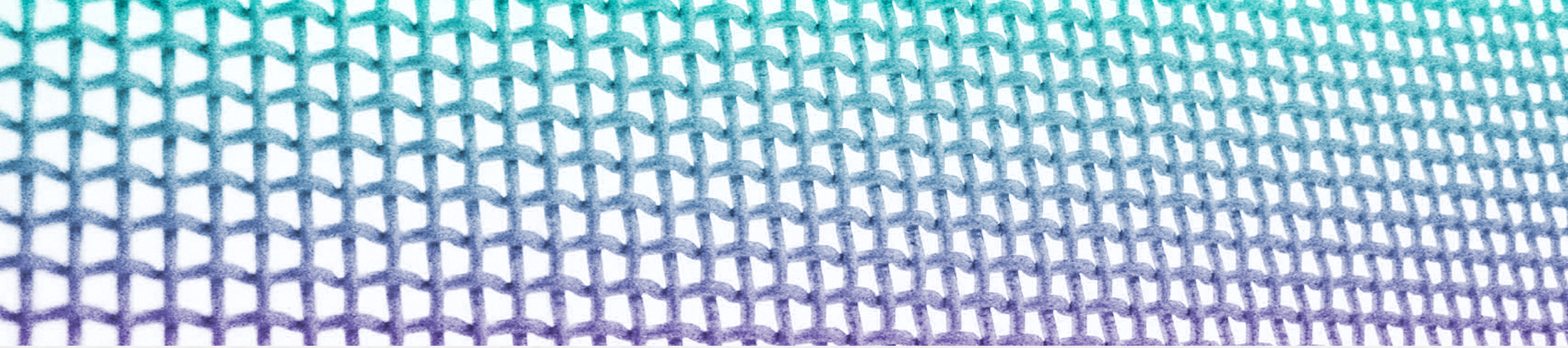
CLASSIFICATION:

WHEN "EQUIVALENCE" MEANS "SAFETY"

The FDA must clear most medical devices before they can be sold to the public. This article refutes a claim that the FDA's process for clearing devices does not provide the "reasonable assurance of safety and effectiveness" Congress intended. The claim, which was first suggested in Medtronic v. Lohr, 518 U.S. 470 (1996), arose because Congress initially grandfathered devices sold before 1976 and then allowed new devices to be cleared if they were "equivalent" to pre-1976 devices. But after 1976, the FDA used medical panels to "classify" devices. Today, most devices are cleared because they are equivalent to post-1976 devices whose safety and effectiveness were independently assessed when they were classified. That assessment provides the reasonable assurance Congress requires and makes the Lohr dictum no longer applicable.

The many well-reasoned explanations as to why the Lohr dictum should no longer be followed have overlooked a fundamental question, which, if asked, greatly strengthens the argument for distinguishing *Lohr*.

That 1996 Supreme Court dictum declared that the "focus" of most of the FDA's medical device regulation process was "not safety." The Court said this because Congress had allowed the FDA to clear for sale new devices "equivalent" to others that had "never been formally reviewed … for safety or efficacy" because



That 1996 Supreme Court dictum declared that the "focus" of most of the FDA's medical device regulation process was "not safety."

they were sold before the medical device law went into effect in 1976[2]. In other words, Congress had grandfathered them.

The idea that the FDA was not focusing on safety is, to say the least, peculiar. Congress has charged it with a duty to provide "reasonable assurance" that medical devices are safe and effective.[3] In recent years, commentators have offered a number of reasons why the FDA today is in fact providing that assurance for the devices it clears. They have pointed to 1990 statutory amendments that strengthened the requirements for clearance and to the FDA's pronouncements about that process.[4] But the idea that the clearance process "is focused on *equivalence*, not safety" has been hard to shake.

These commentators have simply assumed that all clearance through what is called the 510(k) process is based on pre-1976 devices, or, as the General Accounting Office has put it, "iterations" of those devices.[5] In other words, clearance of a new device might be based on equivalence to a post-1976 device, but that device would, in turn, have been cleared as being equivalent to a pre-1976 device, all without any stand-alone look at safety and effectiveness. In answer to the question "equivalent to what?" they have assumed the answer was ultimately a pre-1976 device.

But both the governing statute and the regulatory history provide a different answer for many, if not most, medical devices. In the Act, Congress instructed the FDA to convene medical panels to classify devices. And where after 1976 the FDA classified a device or group of devices as presenting a low or moderate risk, the statute authorized clearance based on equivalence to the classified device.[6] So for these devices, the answer to the question "equivalent to what?" is quite different. It is "equivalent to a device classified by the FDA as being safe and effective."

In order to look at how the classification process has worked, it is helpful to examine the governing law as it has been applied to one particular product group, surgical mesh.

The scheme Congress enacted in 1976 and revised in 1990 requires the FDA to place devices in classes according to the amount of regulation needed to provide "reasonable assurance of safety and effectiveness." Those that need the least are in Class I. Those that may additionally need only what are called "special controls" are placed in Class II. And those whose risks are sufficiently great or unknown are placed in Class III and subjected to special scrutiny and regulation. *See* 21 U.S.C. § 360c(a)(1). But the purpose in all cases is to provide that reasonable assurance.

Congress in 1976 instructed the FDA to create medical panels to classify devices. The panel members, paid for their work, were to be persons who "possess skill in the use of, or experience in the development, manufacture, or utilization" of the devices. 21 U.S.C. § 360c(b)(2). They were to be organized "according to the various fields of clinical medicine and fundamental science in which devices intended for human use are used." 21 U.S.C. § 360c(c)(1). Panels had to explain why Class III treatment was not necessary to provide reasonable assurance of safety and efficacy if they were evaluating devices to be implanted in the human body. 21 U.S.C. § 360c(c)(2). Before the FDA adopted a recommendation, it was to publish the panel recommendations in the Federal Register and invite public comment. Again, if the FDA decided not to place an implantable device in Class III, it was to provide "a full statement of the reasons." 21 U.S.C. § 360c(d)(2)(B).

So it was with surgical mesh.

In 1978, the FDA assigned three classification panels the job of evaluating surgical mesh: General and Plastic Surgery, Orthopedic Device, and Gastroenterology and Urology. They were to classify devices based on "[p]anel members' personal knowledge of, and clinical experience with, the devices under review." 47 Fed. Reg. 2810, 2812 (Jan. 19, 1982). In their deliberations, they considered risks such as infection, foreign body reaction and discomfort. *Id.*

In 1982, the panels recommended that surgical mesh (21 CFR § 878.3300) be placed in Class II. Their report said that surgical meshes have "an established history of safe and effective use." 47 Fed. Reg. 2810, 2817 (Jan. 19, 1982). It said they "meet a generally accepted satisfactory level of tissue compatibility." *Id.* The panels cited medical literature to support their conclusions. *See id.* at 2817-2818.

The FDA tentatively agreed with the classification "because of the extensive clinical usage of surgical mesh over a long period of time and because there is sufficient

The scheme Congress enacted in 1976 and revised in 1990 requires the FDA to place devices in classes according to the amount of regulation needed to provide "reasonable assurance of safety and effectiveness."

information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device." Id. at 2817. The FDA noted that surgical meshes had then been in use for 20 years. *See id.* It cited three studies on the use of polypropylene mesh, and noted that one of them:

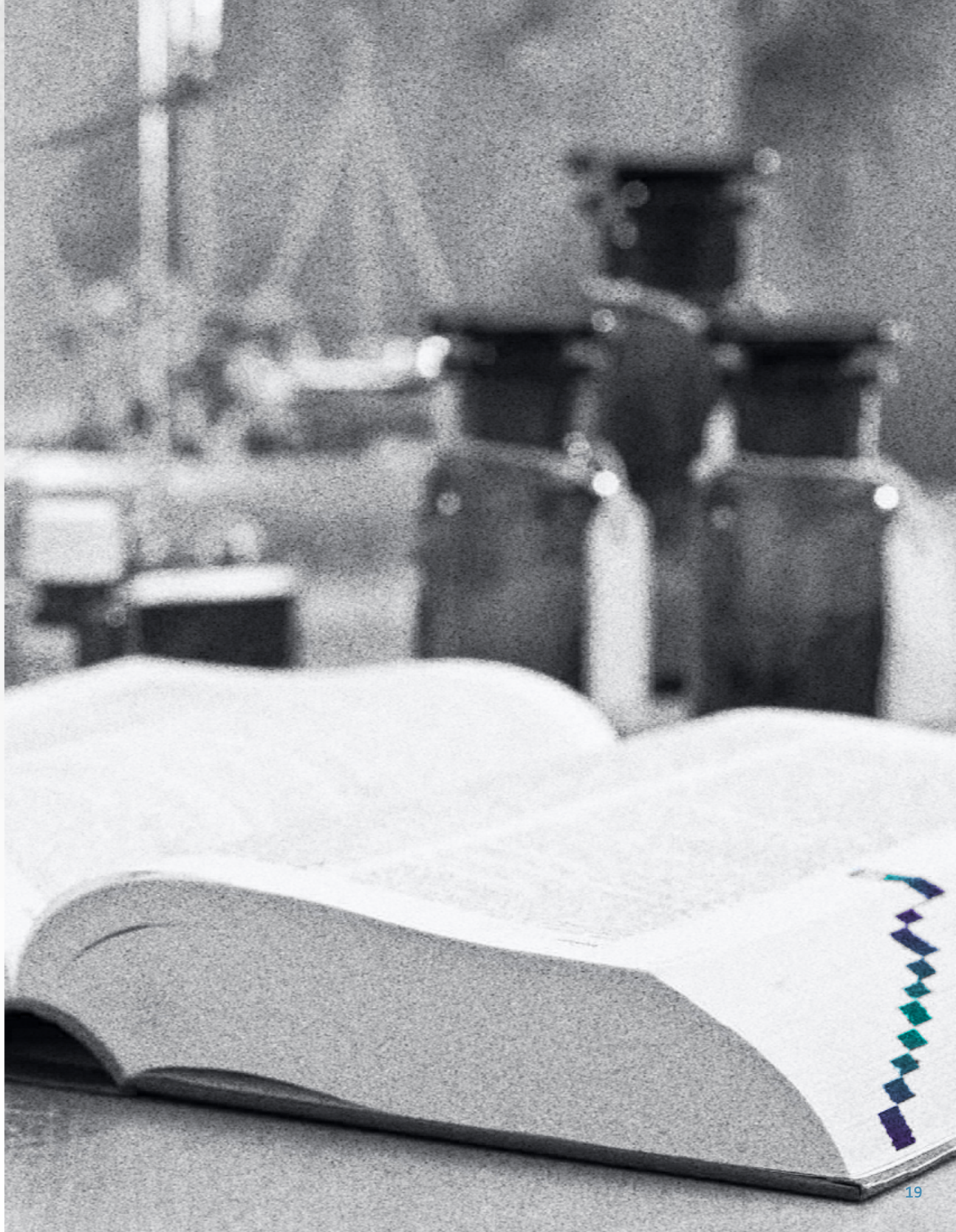
> *reported on 53 patients for the repair of incisional hernias with polypropylene mesh. During 8 years (1970-1978), there was no operative mortality and the mesh had been uniformly well tolerated. The recurrence rate was found to be 11 percent, a distinct improvement over the era before the mesh was used.*

Id. at 2817, citing Gerald M. Larson and Harold W. Harrower, *Plastic Mesh Repair of Incisional Hernias*, 135 American Journal of Surgery 559 (April 1978). That study declared that complications from use of mesh were "rarely serious," that mesh did not increase the frequency of wound infection," and that polypropylene mesh "does not appear to degrade or lose strength in patients." *Larson et al.*, 135 American Journal of Surgery at 562. The FDA also cited an earlier one-year dog study that found a "minimal foreign body reaction" to the mesh.[7] The FDA published the classification along with others and invited public comment.

In 1988, after reviewing the comments and holding public hearings, the FDA published the final classification of surgical mesh as Class II. 53 Fed. Reg. 23856 (June 24, 1988). It rejected a claim that Class II devices were not safe and effective until a performance standard was adopted. *Id.* at 23860. It reiterated that the "biocompatibility of [surgical mesh and certain other devices] "has been established through their successful use for a number of years" and "the probable benefit to health from proper use of these devices outweighs an[y] likelihood of illness or injury resulting from their use." *Id.* at 23861. With respect to surgical mesh, it said Class II performance standards might be needed, however, because "long-term biocompatibility" was still an issue. *Id.* at 23862.

In 1996, Ethicon, Inc. submitted a 510(k) notification for the sale of "Modified PROLENE* polypropylene nonabsorbable synthetic surgical mesh." See http://www. accessdata.fda.gov/scripts/cdrh (K963530)[8]. The predicate device was PROLENE* polypropylene mesh, which was identified as a "Class II Medical Device, 21 CFR §878.3300." The notification describes the product as being composed of knitted filaments "identical in composition" to that used in a suture product whose safety had been approved. It provides the labeling that will be used, including the statement that the material "is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes." It offers no clinical data, other than one 28-day animal test, but recites that the predicate mesh has "a long established history of safe clinical use as an implantable material." The FDA cleared the device.

So for this product, there was, contrary to *Lohr*, a formal expert panel and FDA review of safety and effectiveness, which led to classification of the predicate device. The determination by the FDA that the new product was equivalent in safety and effectiveness was thus an affirmative finding that the new device was, in fact, both safe and effective.



Given the prominent role that classification plays in the statute and in the history, it is worth asking why its role has been overlooked in the debate over *Lohr*. The closest any of the commentators on *Lohr* have come is to say that the FDA system "uses data" in the 510(k) notice to determine classification.[9]

For one thing, some Class III products may still be cleared based on equivalence to pre-1976 devices. Like the device at issue in *Lohr*, they have not been found safe enough to be placed in Class II, yet the FDA has still not required that they go through the approval process.[10]

Another potential problem is that the FDA, when it adopted a regulation identifying devices that qualified for predicate status, did not follow the simple statutory language, which says any post-1976 device "which has been classified in class I or II" can be a predicate.[11] Instead it said devices which "have been reclassified from class III to class II or I," which is narrower and confusing. This is not a problem for surgical mesh, an implantable device, because Congress classified all implantable devices as Class III until a medical panel decided otherwise.[13] But it suggests a narrower group than the statutory language would permit.

Another problem is that the FDA itself has not emphasized the importance of classification when it has defended the 510(k) process. It was only recently that it declared

> *[b]ecause devices are classified according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness, classification of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device.* [14]

Whatever the reason, when any court confronts the *Lohr* dictum, it needs to ask the question "equivalent to what?" If the answer is a device in a group that the FDA and its medical panels have classified as being safe and effective, then the dictum should be reversed, for in that circumstance "equivalence *is* safety."

And there is a broader point. Where Congress has told the FDA how to provide "reasonable assurance" of safety and effectiveness, and the FDA has done what Congress has instructed, it is not within the proper province of a court to disregard what the FDA has done simply because it disagrees with the methods Congress chose. *Lohr* was a peculiar case in which the FDA had not yet done what Congress had told it to do with a Class III product. But where the FDA has acted, its action should be respected. That should be true even when it has classified a device as being so safe as to be entirely exempt from the 510(k) or any other premarket review process. ■

Whatever the reason, when any court confronts the *Lohr* dictum, it needs to ask the question "equivalent to what?" If the answer is a device in a group that the FDA and its medical panels have classified as being safe and effective, then the dictum should be reversed, for in that circumstance "equivalence *is* safety."

1. Butler Snow LLP, Ridgeland, Miss. The firm represents Ethicon, Inc. in mesh litigation.
2. Medtronic Inc. v. Lohr, 518 U.S. 470, 493 (1996).
3. 21 Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013).
4. See Ralph F. Hall and Michelle Mercer, *Rethinking Lohr: does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 Minn. J.L. Sci. & Tech. 737 (2012) (article "questions whether litigants and courts have ignored major statutory and regulatory changes"); James M. Flaherty Jr., *Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process*, 63 Food & Drug L.J. 901, 907-916 (2008) (survey of statutory and regulatory changes). See also FDA, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]/ Guidance for Industry and Food and Drug Administration Staff (2014) at p. 6 ("principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review").
5. GAO, Medical Devices/ FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process 13 (2009).
6. 21 U.S.C.§ 360c(f)(1)(A)(predicate device can be post-1976 device which "has been classified in class I or II").
7. Francis C. Usher, *Hernia Repair with Knitted Polypropylene Mesh*, 117 Surgery Gynecology and Obstetrics 239, (1963). See also B.T. Casebolt, *Use of Fabric Mesh in Abdominal Wall Defects*, 72 Missouri Medicine 71 (1975) (evaluating 35 cases over periods of up to nine years).
8. The entire 510(k) can be found at *Lewis v. Johnson & Johnson*, United States District Court for the Southern District of West Virginia, No. 2:2:12-cv-4301, Dkt. 128-17.
9. *See* Hall and Mercer, supra n.4 at 782 & n. 246 (referring to the "accompanying scientific data" in the 510(k) notice).
10. *See* n.4, supra.
11. 21 U.s.C. 360c(f)(1(A)(i).
12. 21 CFR § 807.92(a)(3).
13. 21 U.S.C. § § 513(c)(2)(C), (d)(2)(B).
14. FDA, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications {510(k)]/Guidance for Industry and Food and Drug Administration Staff (July 28, 2014).

By Luther Munford

By Erin Lane[1]

THINKING BIGGER:

BROADENING REGULATORY STRATEGY FOR NEW MEDICAL DEVICES BY PLANNING FOR BOTH REGULATORY AND REIMBURSEMENT APPROVAL

One day, Michelangelo entered Raphael's studio, and looked at one of young artist's early works. After studying the small painting for some time, Michelangelo wrote across the top of the canvas 'Amplius,' meaning 'greater' or 'larger.' On a small canvas, Raphael's composition was too crowded and narrow, and its impact could only be felt through an expanded composition.

To succeed in bringing new medical technologies to market, manufacturers developing their regulatory strategy would do well to heed Michelangelo's advice: Think Bigger. Specifically, to meet the demands of the "New Health Economy,"[1] a more expansive regulatory strategy must consider reimbursement to ensure the best, most efficient outcome.

Among the many disruptions occurring in the life sciences industry, changes to reimbursement models are placing new pressures on medical device manufacturers. To be sure, enabling speedier patient access to novel innovative devices and demonstrating their value in an already crowded market top the list of challenges.

The concept proposed in this article—combining reimbursement considerations into the development of a regulatory strategy for approval of new medical devices—may not, in and of itself, be novel. However, rapidly evolving reimbursement models lend a new sense of urgency to examining it as a concept and adopting as a tactic.[2]

I. FROM "VOLUME TO VALUE": THE MOVEMENT AWAY FROM FEE-FOR-SERVICE AND TOWARD VALUE-BASED PRICING IS CREATING NEW BARRIERS TO ACCESS OF INNOVATIVE MEDICAL DEVICES

A. CHANGING PAYMENT MODELS FOR HEALTHCARE SERVICES AND PRODUCTS

A growing trend has emerged over how payers reimburse health care providers for their services: payers are moving away from the traditional fee-for-service model, and instead are basing coverage decisions on health outcomes, financial metrics, or some combination.[3] Known as "Pay-for-Performance" or a "Value-Based," such payment models are "the wave of the future."[4] While "value" in health care products and services may lie in the eye of the beholder (patient, doctor, payer), in the New Health Economy, "value" means reducing costs and improving health outcomes.[5]

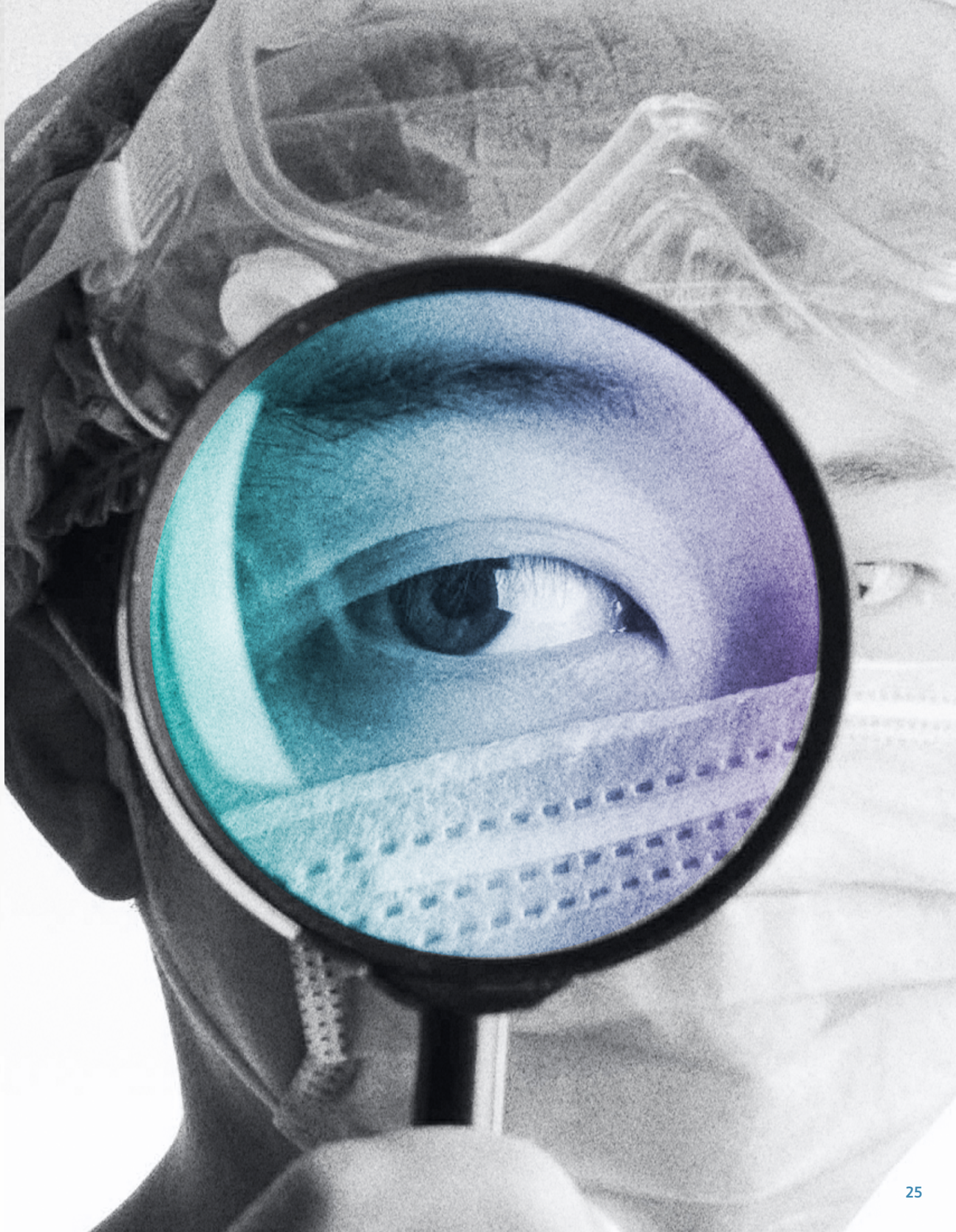
A growing trend has emerged over how payers reimburse health care providers for their services: payers are moving away from the traditional fee-for-service model, and instead are basing coverage decisions on health outcomes, financial metrics, or some combination.

This change has significant implications for introduction of new medical devices and can be addressed through development of an expanded regulatory strategy development. First, uncertainty regarding reimbursement is rising.[6] Payers are imposing more onerous evidentiary requirements to secure coverage of new medical technologies.[7] Increasingly, manufacturers will need to present evidence of "clinical value"—i.e., demonstrating that a new technology is an improvement over the existing standard of care, and "economic value"—when ethical and if the economic impact is significant.[8]

Second, who makes utilization decisions is changing. Under the conventional fee-for-service model, payers act as the gatekeeper to patient access of new medical devices, with health care providers assuming a "countervailing patient advocacy role" to ensure access to new devices.[9] Under a value-based model, providers are, to a degree, reimbursed based on health outcomes and efficiencies.[10] Consequently, a value-based model may actually lead to providers as gatekeepers, resisting adoption and use of new technology.[11]

Third, payers are requiring more evidence and using new metrics to assess new technology and to make coverage decisions.[12] To ensure coverage by payers and utilization by providers, manufacturers of new medical devices will be called upon to demonstrate "evidence across the spectrum of care management and delivery, including outcomes studies, and analyses and evaluations and patient and population-level of alternative care pathways."[13] Likewise, development, selection, and validation of financial and quality-related metrics, and application of evidence to those metrics, will become of paramount importance to the success of new medical devices in a changing industry.[14]

To adapt to this changing landscape, proactive regulatory planning must include early consideration and of gathering the necessary data to support broad reimbursement.



II. "WE HAVE CLEARANCE CLARENCE"[15] ... BUT WHAT ABOUT REIMBURSEMENT?

FDA approval or clearance is a precondition to any public or private payer reimbursement for a new medical device. However, "clearance is no guarantee of coverage" [16] by either CMS or private payers, and more importantly, it is "not equivalent with patients getting access to that device." [17]

Ultimately, decisions regarding regulatory approval or clearance and reimbursement alike depend on evidence gathered to support those decisions. However, the type of evidence gathered at each phase necessarily varies.

A. REGULATORY APPROVAL OR CLEARANCE

FDA approval or clearance is a prerequisite to legally marketing a new device, and the manufacturer must present evidence demonstrating that the device is safe and effective for its intended use. Regulatory strategy for identifying the appropriate path to regulatory approval or clearance is vital to a new product's success, both pre- and post-launch.

Implicit in that regulatory strategy is creating a sound plan for gathering the evidence necessary to submit in support of approval. Clinical trial design, including development and identification of appropriate clinical trial end-points, identification of the targeted patient population, identification of the risks associated with the device and mitigation of those risks, are all within the purview of regulatory strategy.

B. THIRD-PARTY REIMBURSEMENT

FDA approval or clearance is the first significant hurdle that a device manufacturer must overcome on the path to market and patient access, but it does not end the inquiry. Unlike regulatory approval, coverage decisions are ultimately concerned with real-world clinical outcomes, and the costs associated with achieving those outcomes.[18]

To ensure coverage by CMS' Medicare program, for example, a manufacturer must demonstrate that the item covered is "reasonable and necessary for the diagnosis and treatment of illness or injury ..."[19] Thus, to be covered by Medicare, a product, or service must fall into one of the statutorily defined benefit categories and be approved or cleared by the FDA.[20] For private payers as well, a focus on optimizing health outcomes for a defined population and within budgetary constraints leads to collection of evidence different from evidence collected to ensure regulatory approval or clearance.[21]

III. THINKING WITH THE END IN MIND: ENSURING QUICKER PATIENT ACCESS AND REIMBURSEMENT WITH AN EXPANDED REGULATORY STRATEGY

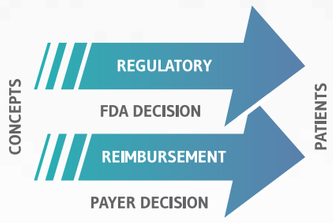
A. SEQUENTIAL VERSUS PARALLEL REGULATORY AND REIMBURSEMENT STRATEGY

Traditionally, the processes of seeking FDA approval or clearance and securing third-party payer coverage are done sequentially.[22] Following FDA's device approval or clearance, payers then assess the new technology and render a coverage decision, as depicted in the diagram below.[23]

As described above, the type of evidence necessary to achieve regulatory approval is different from evidence necessary to secure reimbursement—demonstrating safety and efficacy versus establishing that a new device is reasonable and necessary. What is more, the timing of seeking a coverage decision —after securing regulatory

approval or clearance is different.[24] As a result, this "serial" review process extends both patient access to and a coverage decision regarding a new medical device.[25]

To shorten an otherwise protracted process and to address demands posed by the New Health Economy such as value-based reimbursement, a new tactic has emerged in which regulatory and reimbursement strategy are implemented in parallel, as depicted below.[26]



Effective execution of this strategy requires broader consideration and proactive planning to gather the requisite evidence necessary to collect and to do so earlier. Consequently, the widespread adoption of value-based reimbursement should drive development of a broader regulatory strategy in the New Health Economy.

B. "IT'S ALL ABOUT GATHERING EVIDENCE": FDA'S PARALLEL REVIEW PILOT PROGRAM

As described above, both FDA approval or clearance and third-party payer coverage rely on evidence developed, gathered and analyzed during different phases of the medical device product development cycle. Forming a regulatory strategy that timely accounts for gathering evidence to support both regulatory approval and third-party payer coverage for new devices can lower the barriers to early market access posed by value-based reimbursement models. Indeed, both the FDA and CMS have recognized the importance of this new strategy.

During a November 21, 2014 presentation, FDA's Ken Skodacek presented the slide[27] above, explaining that for FDA, "it's all about gathering evidence," and "if you're gathering evidence for FDA to meet certain needs … I want you to think about gathering evidence for other stakeholders along the way."[28]

Such information gathering had been underscored on October 7, 2011, when FDA and CMS announced their joint "Parallel Review" pilot program. "Under the … program, CMS and FDA offer concurrent review of medical devices for FDA approval and Medicare coverage."[29] FDA described the goal of the pilot program as follows: "Both agencies rely on clinical data in reaching their decisions, and while the two agencies have distinctly different regulatory responsibilities, parallel review can reduce time between FDA approval and Medicare national coverage determinations."[30] Indeed, the program's "linchpin" is the "increased interaction between the primary stakeholders, ideally leading to a clinical trial that meets the needs of all parties involved."[31] Importantly, Parallel Review is designed to reduce the lag between regulatory approval and determination of CMS coverage by as much as six months.[32]

Although innovative, Parallel Review has limitations. Not only is the program voluntary, it is also only available "for qualifying new medical device technologies." Further, only five devices per year can participate in the program.[33] Recently renewed, the program is set to expire on December 18, 2015.[34] Of course, nothing about the pilot program changes the "existing separate and distinct review standards for FDA device approval and CMS coverage determination."[35]

To date, only one device has been approved through the parallel review program. On August 11, 2014, FDA approved Exact Sciences' "Cologuard," the first stool DNA-based colorectal cancer screening test, and simultaneously, CMS issued a national coverage determination (NCD).[36]

C. PARALLEL REVIEW WITH PRIVATE PAYERS: THE FDA REIMBURSEMENT TASK FORCE

In addition to the Parallel Review program, FDA has created a task force on reimbursement, the mission of which is to "[s]treamline the pathway regulatory clearance or approval to reimbursement to support patient access to innovative medical devices."[37] To do so, FDA is working to "[d]evelop a voluntary process that facilitates earlier interactions with payers … about evidence to support coverage and reimbursement."[38] Similar to Parallel Review, FDA is proposing a mechanism whereby device manufacturers can request a pre-submission, confidential meeting with FDA and one or more private payers to shorten the time between device approval and a coverage decision.[39]

Like Parallel Review, nothing about this mechanism changes the method by which FDA evaluates safety and effectiveness.[40] Moreover, the program is voluntarily for manufacturers and payers, with manufacturers inviting payers to attend the pre-submission meeting and otherwise participate in the process.[41]

The benefits of these voluntary initiatives are far-reaching and signal FDA's understanding that all stakeholders need to adapt to industry-wide changes. For patients, FDA's initiatives represent an effort to fulfill its goal of enabling "[e]arlier access to innovative technologies."[42] For payers, these programs represent a chance to obtain earlier information about new technologies, understand the FDA review process, and offer meaningful input into the data and analyses most useful in making coverage decisions.[43] For device manufacturers, they have an early opportunity to understand payers' evidentiary needs in making coverage decisions, evaluate and address coverage-related issues sooner in the regulatory process, and obtain earlier reimbursement decisions.[44]

CONCLUSION

Systemic changes in the New Health Economy are having ripple effects throughout the spectrum of health care. In particular, a shift to value-based reimbursement models means that all stakeholders must identify strategies for reducing costs and improving health outcomes.

For manufacturers developing innovative medical devices in this environment, their regulatory strategy should incorporate reimbursement considerations. Indeed, the two gatekeepers for entry to market—FDA and CMS—have signaled a combined willingness to facilitate the success of new medical technologies by encouraging parallel review of both regulatory approval and coverage. Adopting a broader regulatory strategy to plan for gathering evidence to simultaneously meet the demands of both approval and coverage is an important tactic in establishing and demonstrating the "value" of new medical technologies. ■

1. PwC Health Research Institute, The FDA and industry: A receipt for collaborating in the New Health Economy, Jan. 2015, p. 2.
2. Long, G., et al., "Evolving Provider Payment Models and Patient Access to Innovative Medical Technology," *J. of Med. Econ.*, (Accepted for publication in 2014), pp. 1-2.
3. *Id.*, p. 4.
4. *Id.*, pp. 3-4, 7.
5. PwC Health Research Institute, p. 10.
6. Long, G., et al., p. 10.
7. *Id.*
8. *Id.*
9. *Id.*, p. 11.
10. *Id.*
11. *Id.*
12. *Id.*, pp. 14-15.
13. *Id.*, p. 15.
14. *Id.*, pp. 14-15.
15. Roger Murdock (Kareem Abdul-Jabbar) to Capt. Oveur (Peter Graves) in *Airplane!* (1980).
16. Judith Hickey, "Considering Reimbursement Issues During the Regulatory Planning Process for Product Success," *RA Focus* (June 2006), p. 34.
17. "FDA Task Force Aims to Solve Lag between Device Approval and Reimbursement," *Homecare*, Dec. 19, 2013.
18. Felix W. Frueh, PhD, "Regulation, Reimbursement, and the Long Road of Implementation of Personalized Medicine," *Value in Health* 16 (2013), p. S29.
19. Hickey, p. 33.
20. *Id.*
21. *Id.*; Blue Cross Blue Shield Association Technology Assessment Criteria: http://www.bcbs.com/blueresources/tec/.
22. Ken Skodacek, "Improving Patient Access Through Early Collaboration," FDA/CDRH, Nov. 21, 2014, p. 12.
23. *Id.*
24. *Id.*
25. *Id.*
26. Hickey, p. 32; Frueh, p. S29; Skodacek, p. 12.
27. Skodacek, p. 5.
28. FDA/CDRH Transcript from "Brain-Computer Interface (BCI) Devices for Patients With Paralysis and Amputation," Nov. 21, 2014, pp. 38-39.
29. "FDA, CMS launch pilot program for voluntary parallel review of innovative devices," FDA News Release, Oct. 7, 2011.
30. *Id.*
31. Rothenberg, Stephen, et al., "What Parallel Review Means for Manufacturers," *BIOTech Now*, Mar. 12, 2012.
32. "FDA approves first non-invasive DNA screening test for colorectal cancer," FDA News Release, Aug. 11, 2014.
33. FDA News Release, Oct. 7, 2011.
34. 78 Federal Register 76628, Dec. 18, 2103.
35. "FDA-CMS Parallel Review," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm.
36. FDA News Release, Aug. 11, 2014.
37. Skodacek, p. 10; FDA/CDRH Transcript, pp. 39-40.
38. *Id.*
39. Skodacek, p. 13; FDA/CDRH Transcript, pp. 39-40.
40. Skodacek, pp. 13-15.
41. *Id.*
42. Skodacek, p. 16.
43. *Id.*
44. *Id.*

By Chris Berdy

TEAM MEMBERS

Sidney P. Allen, Jr.
Cara R. Baer
Amanda B. Barbour
James C. Barton, Jr.
James A. Beakes III
Aubrey Beckham
Christopher S. Berdy
Michael L. Brown
Shelly Gunn Burns
Betty Campbell
Paul V. Cassisa, Jr.
Elizabeth E. Chance
Kimberly S. Coggin
David M. Cohen
Charles R. Crawford
Meta C. Danzey
Douglas J. DiPaola, MD
Kathy Doelling
John H. Dollarhide
Mark A. Dreher
Caroline L. Eley
Dan H. Elrod
William M. Gage
Mark W. Garriga
Hemant Gupta
Robin Adams Hall
Charles C. Harrell
John J. Healy III
Michael B. Hewes
Shannon E. Hoffert
Eric E. Hudson
Chad R. Hutchinson
G. Brian Jackson
Charles F. Johnson III
Alyson Bustamante Jones
Brenda Currie Jones
Christy D. Jones
Richelle W. Kidder
Julie Watson Lampley
James J. Lawless, Jr.
Katherine M. Mara
Ashley J. Markham
Alan D. Mathis
Taylor B. Mayes
Laura Raulston McCarthy
W. Jeff McGoff
Julian D. Miller
Anita Modak-Truran
Susanna M. Moldoveanu
Christopher D. Morris
Charles F. Morrow
Jenna C. Newmark
David W. Ohlwein
Sara Anne T. Quinn
Keishunna L. Randall
Aaron R. Rice
Orlando R. Richmond, Sr.
Benjamin W. Roberson
Paul S. Rosenblatt
Ben J. Scott
Machelle Dunavant Shields
Margaret Z. Smith
Hollie A. Smith
Liz Smithhart
Nils B. (Burt) Snell
M. Andrew Snowden
Adam J. Spicer
Noel F. Stahl
Ashley Nader Stubbs
Kari L. Sutherland
Travis B. Swearingen
Rockney S. Taveau
Andrew D. Tharp
Marcus A. Treadway III
Robert L. Trentham
James B. Tucker
J. Kennedy Turner III
Daniel W. Van Horn
Jordan N. Walker
Thomas E. Williams
Virginia B. Wilson
Amanda Haynes Young