



Health Law Section

The Mississippi Bar

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Message from the Chair

MESSAGE FROM THE CHAIR

It is hard to believe that Spring is here already, and that half of my year as Chair of the Health Law Section has passed by already. As I look at the calendar, I see that the Bar Convention is just a little less than four months away. We still have a few events along the way, and I invite you to “save the date” for our upcoming CLE event, which we’ve dubbed once again “Hot Topics in Health Care Law.”

This one-day CLE event is scheduled for Thursday, May 28, 2015, at the Mississippi Bar Center, and it promises to be another good opportunity to catch up on what is going on in our field of practice. Blake Adams with the Phelps Dunbar firm has taken on the task of chairing the CLE committee and the schedule is almost complete. We anticipate another legislative update from our Immediate Past Chair, Stephen Clay, both a primer and update on health care fraud and abuse issues, an ethics update and more. I hope you will plan to join us in Jackson on May 28th.

Again this year, we have decided to join with the Business Law Section for our annual business meeting at the Bar Convention. Julie Mitchell, one of our Executive Committee members, has agreed to present a session on “Government Audits from A to Z, Health Care and Beyond.” This promises to give our members and Business Law Section members some insight into issues

such as Recovery Audit Contractor audits and Zone Program Integrity Audits, just to name a few. Thanks to Julie for agreeing to share this information with us. The joint session will also include a presentation from Assistant Secretary of State Cheryn Baker, who will update us on the new crowdfunding regulations adopted by Secretary of State Delbert Hosemann and his staff. While the SEC is bogged down in its own rule-making process for crowdfunding activities, Mississippi has become the next state to legalize this approach to capital formation. In this era of ubiquitous social media, the next wave in venture capital activity has become crowdfunding, which allows private individuals to raise funding through internet-based funding portals. Health care start-ups will no doubt benefit from the availability of crowdfunding, and Cheryn Baker’s timely remarks will be welcome instruction to both the Health Law Section and the Business Law Section.

By the time the Bar Convention arrives, we should have yet another ruling on provisions of the Affordable Care Act. As recently as March 4, 2015, the Supreme Court heard oral argument in the case of *King v. Burwell*, which deals with a central mechanism of the ACA: tax credit subsidies payable to economically eligible citizens. The Supreme Court will be called upon to decide whether the IRS may permissibly promulgate regulations to extend tax-credit subsidies to coverage pur-



Bob Anderson, Chair

chased through exchanges established by the federal government under Section 1321 of the Affordable Care Act, when the plain language of the statute refers to an “Exchange established by the State.” Without question, the tax credit subsidies are a necessary component to make the ACA work and to eliminate them would then keep many people from being able to purchase health insurance and would result in a disparate number of unhealthy, and therefore more expensive, people in the insurance pool. Thus, once again, the Supreme Court’s anticipated ruling in *King v. Burwell* has the prospect, at least, of gutting the Affordable Care Act.

I appreciate your participation in our Section. I encourage you to contact me or other members of our Executive Committee if you have thoughts or ideas about how we may continue to grow our Section and how we may better serve you. After more than 20 years of practice in health law matters, it remains clear that continuing education in this field is inescapable. I look forward to seeing you in Jackson on May 28th and in Sandestin in July.

Potential FDCA Enforcement Changes

by: Robert G. ("Bob") Anderson, Assistant United States Attorney

For decades, health care practitioners have faced the daunting prospect of strict criminal liability under the Food, Drug and Cosmetic Act (FDCA), set forth at 21 U.S.C. § 301, *et seq.*, for conduct related to handling or purchasing misbranded or adulterated drugs. Government prosecutors with the Department of Justice and investigators with the FDA's Office of Criminal Investigations had been confident that the language of the FDCA did not require any proof of intent or knowledge of the FDCA's prohibitions. The provision used most often, 21 U.S.C. § 331(a), provides for criminal sanctions for any act or causing any act involving "introduction or delivery for introduction into interstate commerce of any food [or] drug . . . that is adulterated or misbranded." While a violation of 331(a) is only a misdemeanor, subjecting a defendant to a maximum one year sentence of imprisonment, the courts have long recognized that the sentences for multiple convictions may be "stacked" so as to require serving consecutive terms for a defendant.

While there was some early question about the scope of § 331(a) and the sweep of its sanctions, in the seminal case of *United States v. Park*, 421 U.S. 658, ended much of the debate. In *Park*, the United States Supreme Court concluded that even a corporate president who was himself uninvolved in the actual conduct leading to the adulteration of food products being stored in a corporate warehouse could be held criminally liable under the provisions of 21 U.S.C. § 331(a). In announcing what came to be known as the "responsible corporate officer" doctrine, the Supreme Court reasoned that if a person is in a position to stop a violation of the FDCA from occurring but the violation occurs in any event, that person may be charged with a crime under the FDCA. *Id.*, 421 U.S. at 676. The Supreme Court explained that when a person volun-

tarily takes a job in an industry regulated by the FDCA, he has a higher duty to protect the public health and may be subjected to strict liability for failure to assure compliance with that duty. *Id.* at 672-673. There remained an exception to this strict liability under § 331(a) after *Park* when a defendant could show that it was objectively impossible for him to have prevented the violation of the Act because he was powerless to do so. *Id.* In the *Park* case, the defendant had not any such showing.

For the past four decades, federal prosecutors have utilized the FDCA to charge physicians who acquired misbranded or adulterated drugs and then dispensed them to their patients with violations of the FDCA under the strict liability provisions of 21 U.S.C. § 331(a). However, the outcome of a recent case in the Eastern District of Tennessee may signal some potential enforcement changes in the Government's use of the FDCA. In the case of *United States v. Anindya Kumar Sen and Patricia Posey Sen*, No. 2:13-cr-56 (E.D.Tenn.), Sixth Circuit Appeal Nos. 14-5772 and 14-5786, the Government had charged Dr. Sen and his wife with causing the introduction into interstate commerce of misbranded drugs under § 331(a). At trial, the jury convicted both defendants on multiple misdemeanor counts and the district court sentenced them each to terms of imprisonment, including "stacked" terms for Dr. Sen. On appeal, Dr. and Mrs. Sen challenged their convictions and argued, *inter alia*, that § 331(a) should not apply to them because they did not cause the introduction of the misbranded drugs into interstate commerce and because the strict liability aspect of their convictions was too harsh because they were powerless to prevent the shipment of the misbranded drugs they received from a supplier. While the Government did not directly respond to this argument, it did take an inter-

esting tactic in response to the appeal in the Sen case: the Department of Justice, through the Civil Division's Appellate Section, moved to remand the Sen case to the district court, where the prosecutor then moved to dismiss the indictment with prejudice. Thus, the convictions in the Sen case were wiped away, even though it appeared at the outset that the Sen case was just like dozens and dozens of earlier cases in which the Department of Justice prosecutors had followed the same process and procedure in obtaining convictions.

Whether the result in the Sen case signals a potential change in FDCA enforcement efforts by DOJ in the form of a retreat from use of § 331(a) is yet to be seen. But if it should develop that § 331(a) will no longer be used as aggressively and routinely by prosecutors, this could be good news for health care providers. First and foremost, they will be relieved of the necessity of defending these strict liability charges. Additionally, in the absence of the strict liability tool of § 331(a), the Government will be forced to rely upon an alternative FDCA provision, such as 21 U.S.C. § 331(c), which criminalizes the receipt in interstate commerce of adulterated or misbranded drugs. More importantly for health care providers, § 331(c) appears to offer the potential defendant a good faith defense under another section of the FDCA, 21 U.S.C. § 333(c), which provides an exception to the criminal penalty for receipt of misbranded drugs if a person received misbranded or adulterated drugs and then delivered them in good faith. It is likely that prosecutors will be somewhat reluctant to bring charges which provide for a good faith defense at the outset.

The actual impact of the result in the Sen case is not yet clear. It is likely that the Government may argue that it is an isolated case, a matter *sui gen-*

Potential FDCA Enforcement Changes, *continued*

eris, which the courts should give little attention. Defendants in earlier cases might argue that it should have some impact on their convictions, but the Government will likely oppose any such arguments. Another curious side note is that FDCA charges have routinely been combined with health care fraud charges and have been included

in False Claims Act cases. Another recent decision, *United States v. Omnicare*, 745 F.3d 694 (4th Cir. 2014), suggests that misbranding allegations are not ripe for treatment under the False Claims Act because compliance with the FDCA is not one of the terms and conditions of participation in Medicare and Medicaid.

Health care counsel should be aware of the result in the Sen case and be vigilant in watching to see how DOJ proceeds with its use of the FDCA in the wake of Sen. There may well be changes in the future in what had been a routine use of § 331(a) of the FDCA.

Hot Topics in Health Care Law - A CLE Briefing

The Mississippi Bar's Health Law Section presents:

Hot Topics in Health Care Law – A CLE Briefing

Thursday, May 28, 2015 - MS Bar Center - 643 North State Street - Jackson

\$150 for Health Law Section Members / \$200 Non-Section Members

6 Hours CLE Credit, including 1 Ethics Hour

[Seminar Brochure and Agenda](#)

About the Seminar:

Health Care Law is a constantly changing area of the law. Business arrangements which are commonplace in other industries can lead to draconian penalties and even prison time under the increasingly harsh and complex web of state and federal regulations that healthcare providers and suppliers must navigate. Individuals and businesses are faced with increasing uncertainty in the health insurance markets due to the potential outcome of litigation related to the implementation of the Affordable Care Act. Health care providers who have had claims denied face a lengthy administrative appeals process. No matter what area of law you practice, there always seems to be new hot topics in health care law which may impact your clients. This 6.0 hour CLE credit seminar, including one hour of ethics credit, will cover some of the current hot topics.

During this CLE Seminar, Past Chair of the Health Law Section Stephen Clay will offer an update on health care issues addressed during the 2015 session of the Mississippi Legislature. Jeff Moore and Blake Adams of Phelps Dunbar LLP will outline the numerous ways that healthcare providers and suppliers can “break bad” as they speak on state and federal fraud and abuse laws. Brant Ryan and Allison Jones of Gilchrist Donnell PLLC will offer their insight on the employer mandate under the Affordable Care Act and the potential implications of the United States Supreme Court's upcoming decision in *King v. Burwell*. Assistant United States Attorney Bob Anderson will provide invaluable perspective from the enforcement side as he speaks on recent developments in healthcare fraud and the False Claims Act. Janet McMurtray of Purdie & Metz PLLC, who represents the Mississippi Division of Medicaid on Medicaid claims appeals, will provide practical advice and pointers as she covers the ins and outs of the Medicaid appeals process. Finally, The Mississippi Bar's General Counsel, Adam Kilgore, will present an ethics hour on client trust account management.

This seminar will provide timely information to health care lawyers as well as to general practitioners with health care and non-health care business clients. We hope to see you at the Mississippi Bar Center on Thursday, May 28.

[Click here to register and pay by check or credit card.](#)

Health Law Section

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We are on the
web!
Click [here](#)

Upcoming Events

Thursday, May 28, 2015
6 hour CLE at the Mississippi Bar Center
in Jackson.

Thursday, July 9, 2015
Health Law Section Annual Meeting at
the Sandestin Hilton.

Health Law Section 2014-2015 Executive Committee

Write for the Health Law Section Newsletter

The Health Law Section newsletter is now accepting articles on health law topics for publication in the newsletter. If you have an idea for an article, you may submit it to Health Law Section Newsletter Editor Jenny Tyler Baker at Jenny@tindelllawfirm.com.

Please include a short description of the article. The Health Law Section Committee will consider your proposal and will notify you of whether your proposal has been accepted. The committee reserves the right to reject proposals. Please note that when you submit your article for publication in the newsletter, you will be granting The Mississippi Bar the nonexclusive right to publish your article.

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