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Pharmacy Compounding after the Drug Quality and Security Act

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THE HEALTH LAWYER

IN THIS ISSUE

Pharmacy Compounding After The Drug Quality and Security Act 1

Chair's Column..... 2

The Impact of Immigration Reform on the Healthcare Sector 9

Section News..... 16

The Demise of DOMA: Windsor's Effect on Employee Benefits..... 19

Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road..... 24

2-Midnight Rule Update: Hospitals Must Continue Implementation of the 2-Midnight Rule 34

Section Calendar..... Back Cover

PHARMACY COMPOUNDING AFTER THE DRUG QUALITY AND SECURITY ACT

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On November 27, 2013, President Obama signed into law the Drug Quality and Security Act ("DQSA"), which amends the Federal Food, Drug, and Cosmetic Act ("FDCA") to add statutory provisions addressing drug compounding and supply chain issues. This article discusses Title I of this legislation, known as the Compounding Quality Act, and draft compounding guidances subsequently issued by the Food and Drug Administration ("FDA"). Section I provides a brief history of FDA's regulation of compounding activities before the Compounding Quality Act's enactment. Section II reviews the Compounding Quality Act and FDA's new draft guidances. Section III considers some of the questions left unanswered by the new legislation.

History of FDA's Regulation of Drug Compounding

Regulation of Compounding Prior to 1997

The FDCA gives FDA broad statutory authority to regulate the manufacture of new drugs, a category that also includes most biologics.¹

Section 505(a) of the statute prohibits the introduction of unapproved new drugs into interstate commerce. Under the FDCA, a "new drug" is a drug "the composition of which is such that such drug is not generally recognized...as safe and effective" for the uses prescribed, recommended, or suggested in its labeling.² Once FDA approves either the new drug application ("NDA") or biologics license application ("BLA") for a new drug, the manufacture of that drug is subject to FDA regulations. FDA considers drug manufacturing to include a broad scope of activities and defines the term "manufacturing" to include the "making" of a drug "by chemical, physical, biological, or other procedures."³ In addition to the premarket approval required for a new drug, the agency imposes substantial additional obligations on drug manufacturers, including registration,⁴ compliance with current good manufacturing practices ("GMPs"),⁵ submission to establishment inspection,⁶ and product labeling requirements.⁷

The traditional compounding of drugs, also known as pharmacy compounding, is the process by which drug ingredients are combined, mixed, or altered by a pharmacy in order to create a medication that is designed to meet an individual patient's needs.⁸ This process is understood as "traditional"

Pharmacy Compounding After The DQSA

continued from page 1

compounding because it is a component of traditional pharmacy practice,⁹ one that allows patients to obtain medically viable alternatives when they cannot take a prescription medicine in its commercially available form. Classic examples of pharmacy compounding include a medication compounded for a patient who is allergic to an ingredient in a commercially available product, or a medication whose dosage has been diluted for a pediatric patient.¹⁰ Traditional pharmacy compounding is distinct from a practice known as “large-scale compounding.” Large-scale compounders, also referred to as “outsourcing facilities,” produce large quantities of drugs, through compounding, without individual patient prescriptions.

Compounding – whether conducted in a pharmacy for individual patients or in an outsourcing facility on a large-scale basis – implicates the new drug approval provisions of the FDCA. In particular, compounded drugs constitute “new drugs” under the FDCA’s definition of the term because they are not generally recognized as safe and effective (nor have their safety and effectiveness been verified). Because compounded drugs constitute “new drugs” and lack approved NDAs, the manufacture and marketing of compounded drugs constitute the manufacture and marketing of unapproved new drugs.

Although FDA clearly has authority to proceed against the shipment of unapproved new drugs, it takes the general position that it does not regulate either the practice of pharmacy or the practice of medicine, which fall within the purview of the states.¹¹ This fact, combined with the lack of explicit provisions in the statute addressing compounding *per se*, has complicated FDA’s efforts in this area.

FDA has historically exercised enforcement discretion with respect to traditional pharmacy compounding,

recognizing the “important public health function” served by “meeting the specialized needs of individual patients for whom commercially available approved drugs are inadequate or inappropriate.”¹² Although pharmacies are still subject to FDA’s general prohibitions against the adulteration of drugs¹³ and false or misleading drug labeling,¹⁴ they are largely exempt from the agency’s broad statutory inspection authority under what is known as the “pharmacy exemption.” A pharmacy qualifies for this exemption if it complies with state law, dispenses drugs upon prescription, and does not “through a subsidiary or otherwise, manufacture...drugs or devices for sale other than in the regular course [of its retail pharmacy business].”¹⁵

FDA has not exercised the same enforcement discretion for large-scale compounding facilities. The agency has openly focused its enforcement efforts on “establishments that produce large quantities of unapproved new drugs under the guise of traditional compounding, and establishments whose activities result in significant violations of the new drug, adulteration, or misbranding violations of the FDCA.”¹⁶ To reinforce the distinction between permissible and impermissible compounding, FDA issued a Compliance Policy Guide (“CPG”) in 1992 that listed factors the agency would consider when determining whether a pharmacy operated outside the scope of traditional compounding practice.¹⁷ This CPG remained in effect until Congress enacted the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), which amended the FDCA to add section 503A. This statutory provision created a safe harbor for traditional pharmacy compounding, which had previously existed under FDA’s “pharmacy exemption,” and codified FDA’s framework set out in the 1992 CPG for identifying impermissible, non-traditional compounding activities.

FDA’s Unclear Enforcement Authority Under Western States

The complex regulatory landscape for compounding that set the stage for the DQSA stems in large part from legal uncertainty surrounding section 503A. Section 503A included restrictions on the solicitation and advertisement of pharmacy compounding services.¹⁸ In *Western States Medical Center v. Shalala*, a group of pharmacies challenged section 503A(c) – and a Nevada federal district court agreed – as infringing their constitutional right to free speech.¹⁹ The Ninth Circuit Court of Appeals affirmed the Nevada court’s decision but also held that the speech restrictions were non-severable, thus invalidating section 503A as a whole.²⁰ Several years later, the Fifth Circuit Court of Appeals arrived at the opposite conclusion and held in *Medical Center Pharmacy v. Mukasey* that the solicitation and advertising provisions, although unconstitutional under the First Amendment, were severable from the rest of section 503A.²¹

In 2002, after the Ninth Circuit’s decision in *Western States* invalidating all of section 503A but before the split with the Fifth Circuit emerged in the *Medical Center Pharmacy* decision, FDA issued a revised CPG articulating its policy on the practice of pharmacy compounding.²² The agency’s policy remained similar in most respects to section 503A, with the notable exception of the solicitation and advertising restrictions struck down as unconstitutional. In a departure from FDA’s enforcement policy before the *Western States* decision, the revised CPG no longer considered solicitation or advertising to be one of the factors that would trigger FDA enforcement action. Nevertheless, the 2002 CPG, like previous FDA statements, reiterated the agency’s commitment to targeting compounding establishments

continued on page 4

Pharmacy Compounding After The DQSA

continued from page 3

“engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the [FDCA].”²³

After the Fifth Circuit’s *Medical Center Pharmacy* decision revived section 503A, however, FDA’s own position on compounding was split. The agency announced that it was “evaluating” the Fifth Circuit’s opinion but, in the meantime, would “follow the court’s decision in the Fifth Circuit and with respect to the plaintiffs covered by the decision.”²⁴ Therefore, for large-scale compounders located within the Fifth Circuit’s jurisdiction, FDA would base its regulatory authority on section 503A, with the advertising and solicitation restrictions severed from the statute. In other jurisdictions, the agency would “continue to follow the enforcement approach reflected in the [revised 2002 CPG].”²⁵ Before the recent legislative activity surrounding compounding, however, FDA issued no official policy statements regarding how the agency would resolve the circuit split and approach enforcement actions brought against compounders.

The Compounding Quality Act and FDA Compounding Draft Guidance Documents

The Compounding Quality Act marks the culmination of legislative efforts initiated in the wake of the meningitis outbreak in October 2012 that resulted in 48 deaths, stemming from a product compounded by the New England Compounding Center (“NECC”).²⁶ Although members of Congress blamed FDA for not regulating NECC more closely, FDA Commissioner Margaret Hamburg contended in hearings before House and Senate committees that confusion existed about whether FDA or state

authorities held responsibility for regulating such compounding facilities.²⁷

Compounding Quality Act

The Compounding Quality Act addresses the controversy surrounding compounding by amending the FDCA in two ways: (1) codifying the distinction between traditional and non-traditional compounding by establishing a category of “outsourcing facilities” subject to a new statutory scheme at the compounder’s option;²⁸ and (2) removing the unconstitutional restrictions on solicitation and advertising in section 503A, thus resolving the circuit split over severability.²⁹

Under the new section 503B of the FDCA,³⁰ a compounder may voluntarily subject itself to FDA regulation by registering with the agency as an outsourcing facility. An “outsourcing facility” is “a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements [in section 503B].”³¹ An outsourcing facility need not have a pharmacy license, and it may compound *without* prescriptions for individual patients.³²

If a compounder elects to register with FDA as an outsourcing facility, it is exempt from the FDCA requirements relating to NDA approval³³ and supply chain,³⁴ as well as the requirement that the labeling of the drugs that it ships bear adequate directions for use,³⁵ as long as it satisfies the conditions set out in section 503B. Unlike traditional pharmacy compounders who satisfy the conditions in section 503A, however, outsourcing facilities are *not* exempt from GMP requirements. Outsourcing facilities must also comply with annual registration,³⁶ regular reporting,³⁷ and adverse event reporting³⁸ requirements, and they are subject to FDA inspection.³⁹

Section 503B also spells out standards for materials that may be compounded at registered outsourcing facilities. Like traditional pharmacy compounders, outsourcing facilities may not compound drugs that are “essentially a copy of one or more approved drugs”⁴⁰ or that present “demonstrable difficulties” for compounding.⁴¹ The statute also imposes conditions on the compounding of bulk substances, although the standard for outsourcing facilities is more stringent than that for traditional pharmacy compounders.⁴² Both sections 503A and 503B rely on FDA to establish lists of accepted bulk substances and drugs presenting demonstrable difficulties for compounding.⁴³

The Compounding Quality Act establishes a system of “enhanced communication” between state boards of pharmacy and FDA, which is a novel development.⁴⁴ The House floor debate suggests that, by making this provision mandatory, Congress hoped to encourage “meaningful communication”⁴⁵ between FDA and state boards of pharmacy as a way to “remedy one of the major problems that surfaced in the NECC situation – a lack of effective communication between State boards of pharmacy and the FDA.”⁴⁶ Section 105 of the statute contemplates that state boards of pharmacy will report to the Secretary of Health and Human Services enforcement actions taken against compounding pharmacies and other “concerns that a compounding pharmacy may be acting contrary to section 503A.”⁴⁷ FDA must notify state boards of pharmacy when it receives notice of a state enforcement action against a compounding pharmacy and whenever it determines that a pharmacy is in violation of section 503A.⁴⁸

FDA Compounding Draft Guidance Documents

Within days of the Compounding Quality Act’s enactment, FDA released three draft guidance documents relating

to the statute. Although these documents address procedural (rather than substantive) issues, this quick publication reflects the seriousness with which the agency views its role in the regulation of drug compounding.

*Pharmacy Compounding of Human Drug Products Under Section 503A*⁴⁹

The first draft guidance applies to traditional pharmacy compounding regulated under section 503A of the FDCA, rather than to the outsourcing facilities newly recognized under the Compounding Quality Act. Like the new statute, however, this draft guidance ties up loose ends left by the circuit split over section 503A by withdrawing the 1998 and 2002 CPGs related to compounding.⁵⁰ The draft guidance also reiterates FDA's expectation that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding.⁵¹

As for FDA's own enforcement actions, the draft guidance indicates that the agency "expects to employ a risk-based enforcement approach," under which "the highest enforcement priority" will be given to compounded drugs and violations posing "the greatest public health risks."⁵² The draft guidance explains that enforcement actions may be brought against pharmacy compounding regulated under section 503A for violations such as misbranding or the production of adulterated or unapproved new drugs.⁵³

Interim Product Reporting Under Section 503B⁵⁴ and Registration Under Section 503B⁵⁵

FDA's second draft guidance addresses the reporting requirement that applies to outsourcing facilities that have elected to register under section 503B. The agency indicates in this draft guidance that it encourages establishments intending to operate as outsourcing facilities to register with FDA "immediately."⁵⁶ According

to the draft guidance, if a facility registers before June 2, 2014, the agency does not intend to enforce the initial registration reporting requirement set out in section 503B "immediately," as long as the facility submits its report within two months of the initial registration.⁵⁷ In its third draft compounding guidance, FDA outlines the criteria and requirements for outsourcing facilities to register on a voluntary basis under section 503B.

Discussion

Many have praised the new statutory provisions as enhancing FDA oversight of non-traditional compounders through express authority to impose GMP and adverse event reporting requirements, among other things. A better reading, however, might be that it undermines FDA's authority. Not only is the registration scheme voluntary, but FDA had authority over non-traditional compounding under section 505 *before* Congress enacted the statute. Indeed, the agency's actions in connection with the meningitis outbreak linked to compounding by NECC proves the point. Arguably, the net effect of this law is to *remove* regulatory tools (such as the NDA requirement) from FDA's arsenal with respect to large-scale compounding businesses.

Not surprisingly, much of the regulated industry, i.e., those subject to rigorous NDAs and abbreviated new drug applications ("ANDAs"), opposed the creation of a separate and less-regulated "outsourcing facility" category.⁵⁸ Moreover, Commissioner Hamburg commented in early December that the scheme "does not provide FDA with all the additional authorities sought."⁵⁹ Further, some concerns articulated by the Government Accountability Office ("GAO") in July 2013 – prior to enactment – remain valid. These include the fact that outsourcing facilities may hold themselves out as "FDA-registered," which could confuse consumers and

physicians about the extent of oversight of the facilities (in particular, lead to inferences of FDA approval). The GAO also noted the lack of consistent oversight across all 50 states, which may continue to be an issue, because the Compounding Quality Act assumes – but does not guarantee – significant state participation in the regulatory scheme.⁶⁰ Two points thus emerge. First, many stakeholders sought something more than (or different from) what was ultimately enacted. Second, the fact that the statute arguably weakens FDA's authority in this very important public health area may not have been fully appreciated by all stakeholders.

One important question that stakeholders have raised since enactment is whether and how non-traditional (large-scale) compounders will be persuaded to register voluntarily for FDA oversight under the new scheme.⁶¹ There are at least two possibilities. *First*, some have speculated that payors (such as hospitals) will require large scale compounding facilities to register with FDA.⁶² FDA is reported to be "pushing hard" for hospitals to buy drugs compounded by facilities that have registered with the agency.⁶³ Other than these market-type forces, another possibility is the use of payment policies (i.e., limiting reimbursement to compounded drugs from registered facilities).⁶⁴ Of course, the fact that registration effectively provides a safe harbor from enforcement action under section 505 (the NDA requirement) may also be persuasive. Comments from some interstate compounding facilities that they might register in order to eliminate uncertainty over who oversees them are off the mark, because there was no question prior to the statute that all compounding constitutes manufacture of a new drug and that large enterprises were squarely within FDA's jurisdiction.

FDA's substantial outreach efforts in the short time since the Compounding Quality Act's

continued on page 6

Pharmacy Compounding After The DQSA

continued from page 5

enactment show that the agency views the initial phase of outsourcing facility registration as a critical moment for the new statute. The agency has already sent letters to governors, health departments, boards of pharmacy, and hospital purchasers asking that they help FDA encourage large-scale compounders to register.⁶⁵ FDA has also contacted hospitals to pledge the agency's strict oversight of registered facilities and launched an online database that identifies registered outsourcing facilities.⁶⁶ As of early March, this list includes 33 facilities, although a few of the registered facilities are different locations of the same outsourcing conglomerate. Whether and to what extent large-scale facilities will continue to register remains an important question and could ultimately prompt new legislation, particularly if FDA otherwise lacks sufficient resources for enforcement actions against those who do not register.

Perhaps the most important interpretive question is what constitutes a copy of an approved drug. The Compounding Quality Act defines the term "essentially a copy of an approved drug" as, among other things, "a drug that is identical or nearly identical to an approved drug,"⁶⁷ unless the approved drug appears on the drug shortage list in effect under section 506E of the FDCA. This is consistent with administrative use of the phrase in FDA's 2002 CPG, prior to the statute's enactment.⁶⁸ For instance, the agency's 2006 warning letter to the NECC cited the facility's manufacture of trypan blue ophthalmic solution and 20 percent aminolevulinic acid solution, both of which were commercially available.⁶⁹ According to the warning letter, the compounded versions of these solutions constituted copies of commercially available drugs.⁷⁰ The agency's interpretation of "essentially a copy" will draw an important line for enforcement purposes. At the very least, this phrase should be

interpreted to mean that large-scale compounding must not be a way of obtaining a "generic" version of an innovator product that still has patent protection or data exclusivity. This would circumvent intellectual property rights, thereby seriously undermining incentives to innovate in medicine and therefore ultimately harm patients in need of new medicines.

Various other questions and implementation tasks remain open. For instance, recent press reports suggest FDA is developing a memorandum of understanding for use with the states, which would in some fashion limit interstate shipment of compounded drugs.⁷¹ It remains to be seen how the state boards of pharmacy will react, or how "meaningful" the "enhanced communications" between federal and state governments will be. The agency will soon need to clarify the manufacturing requirements that apply to outsourcing facilities. Answers to these and other outstanding questions may be forthcoming this year, as FDA representatives have indicated that the agency considers compounding to be a priority and will be "moving aggressively forward" to implement the Compounding Quality Act.⁷² The agency has made good on its promise by issuing warning letters to two outsourcing facilities for manufacturing unapproved new drugs that were also misbranded because the facilities did not receive individual prescriptions for these drugs.⁷³

Conclusion

The Compounding Quality Act was enacted as a way to regulate large-scale compounders like the NECC, which operate largely in the shadows of the prescription drug market. On balance, however, the new statute does not provide FDA the additional authority that it sought and that the innovator and generic

industries supported. There are also very important questions about whether the registration program will be used and, if not, whether FDA will be able to effectively oversee (and institute enforcement action against) large-scale compounders who operate outside the voluntary scheme. If another public health crisis like the meningitis outbreak linked to NECC occurs, stakeholders will likely return to Congress for additional legislation. Congress must regularly re-authorize FDA's ability to collect fees from new drug applicants,⁷⁴ and the upcoming round of negotiations leading to reauthorization in 2017 may provide a suitable opportunity for revisiting the issues.

The views expressed in this article are solely those of the authors and do not necessarily reflect the views of the firm or its clients.



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Endnotes

- 1 FDCA § 505(a).
- 2 See FDCA § 201(p).
- 3 21 C.F.R. § 207.3(a)(8).
- 4 *Id.* § 510.
- 5 *Id.* § 501(a)(2)(B).
- 6 *Id.* § 704.
- 7 *Id.* § 502.
- 8 *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 360-61 (2002).
- 9 *Id.*
- 10 Letter from Steven Silverman, Acting Deputy Director, FDA, to Paul Hughes, Adrian Oleck and Mark Pilley (May 11, 2006), at 1, available at www.finance.senate.gov/newsroom/chairman/release/?id=df2a76ac-2f16-4c4b-9d68-cbf58754ae30.
- 11 GAO, Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight (Oct. 2000), at 17.
- 12 Letter from Steven Silverman, *supra* note 10, at 4.
- 13 FDCA. § 501 (a)(2)(A).
- 14 *Id.* § 503(b)(2).

- 15 *Id.* § 704(a)(2)(A).
- 16 Letter from Steven Silverman, *supra* note 10, at 4.
- 17 FDA CPG, Section 7132.16 (later renumbered section 460.200), Pharmacy Compounding (March 16, 1992); see also *Thompson v. Western States*, 535 U.S. at 362-63. "The Guide listed nine examples of activities that the FDA believed raised such concerns and that would therefore be considered by the agency in determining whether to bring an enforcement action. These activities included: 'soliciting business (e.g., promoting, advertising, or using salespersons) to compound specific drug products, product classes, or therapeutic classes of drug products'; 'compounding, regularly, or in inordinate amounts, drug products that are commercially available...and that are essentially generic copies of commercially available, FDA-approved drug products'; using commercial scale manufacturing or testing equipment to compound drugs; offering compounded drugs at wholesale; and 'distributing inordinate amounts of compounded products out of state.'" *Id.* at 363 (citation omitted).
- 18 FDCA § 503A(c) (repealed in 2013).
- 19 *Western States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1309 (D. Nev. 1999).
- 20 *Western States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001).
- 21 *Med. Ctr. Pharm. v. Mukasey*, 536 F.3d 383 (5th Cir. 2008). Although the Supreme Court ultimately agreed with the Ninth Circuit that section 503A's restrictions on solicitation and advertising violated the First Amendment, the justices did not address the question of severability. *Thompson v. Western States*, 535 U.S. 357, 360 (2002).
- 22 FDA CPG, Section 460.200, Pharmacy Compounding (May 2002) (rescinded 2013). The 2002 CPG explains that the agency was still "considering the implications of [the *Western States*] decision and determining how it intend[ed] to regulate pharmacy compounding in the long term," but that it "recognize[d] the need for immediate guidance" and was, therefore, explaining its "current thinking" about "what types of compounding might be subject to enforcement action under [the then] current law."
- 23 *Id.*
- 24 FDA, *Medical Center Pharmacy v. Mukasey*, available at www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/PharmacyCompounding/ucm134919.htm, accessed through Wayback Machine.
- 25 *Id.*
- 26 Derrick Gingery, *FDA Compounder Inspections May Help Set New Enforcement Standard*, The Pink Sheet (Mar. 11, 2013).
- 27 Derrick Gingery, *Compounding the Problem: Congress, FDA Argue Over Regulatory Responsibility* (Nov. 19, 2012).
- 28 FDCA § 503B(a).
- 29 Compounding Quality Act § 106.
- 30 The Compounding Quality Act redesignated the previous section 503B as the new section 503C.

- 31 FDCA § 503B(d)(4).
- 32 *Id.*
- 33 *Id.* § 505.
- 34 *Id.* § 582.
- 35 FDCA § 502(f)(1).
- 36 *Id.* § 503B(b)(1).
- 37 *Id.* § 503B(b)(2).
- 38 *Id.* § 503B(b)(5).
- 39 *Id.* § 503B(b)(4). These inspections will take place on a "risk-based schedule" established by FDA, which will be based on factors set out in the statute.
- 40 *Id.* § 503B(a)(5).
- 41 *Id.* § 503B(a)(6).
- 42 See *id.* § 503B(a)(2).
- 43 FDA has proposed both lists. See FDA, Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Request for Nominations, 78 FED. REG. 72838 (Dec. 4, 2013); FDA, Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Request for Nominations, 78 FED. REG. 72840 (Dec. 4, 2013).
- 44 See generally Compounding Quality Act § 105.
- 45 159 CONG. REC. H5946, H5960 (statement of Rep. Upton).
- 46 *Id.* at H5961 (statement of Rep. Waxman).
- 47 *Id.* § 105(a) ("The Secretary shall receive submissions from State boards of pharmacy...").
- 48 *Id.* § 105(d). States have also played a role in bringing enforcement actions against outsourcing facilities. Massachusetts, for example, has shut down large-scale compounders for failing to comply with state regulations. See Abby Goodnough, "Massachusetts Orders Another Pharmacy to Close," THE NEW YORK TIMES (Oct. 28, 2012).
- 49 FDA, Draft Guidance – Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (Dec. 2013), available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf.
- 50 *Id.* at 2.
- 51 *Id.* at 3.
- 52 *Id.* at 8.
- 53 *Id.* at 7-8.
- 54 FDA, Draft Guidance – Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Dec. 2013), available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377050.pdf.
- 55 FDA, Draft Guidance – Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Dec. 2013), available at www.fda.gov/downloads/Drugs/

continued on page 8

Pharmacy Compounding After The DQSA

continued from page 7

- GuidanceComplianceRegulatoryInformation/
Guidances/UCM377051.pdf.
- 56 *Id.* at 3.
- 57 *Id.*
- 58 See, e.g., Alaina Busch, “PhRMA Criticizes Senate Drug Compounding Bill As Others Also Take Sides,” *INSIDEHEALTHPOLICY* (Jul. 18, 2013); Derrick Gingery, “GPhA, BIO Join in Outlining Problems With House Compounding Bill,” *THE PINK SHEET DAILY* (Sept. 16, 2013).
- 59 Margaret A. Hamburg, “New Law Enhances Safety of Compounded Drugs and Protection of the Drug Supply Chain” (Dec. 2, 2013), available at www.blogs.fda.gov/fdavoices/index.php/2013/12/new-law-enhances-safety-of-compounded-drugs-and-protection-of-the-drug-supply-chain.
- 60 GAO, “DRUG COMPOUNDING – Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight” (July 2013), available at www.gao.gov/assets/660/656388.pdf.
- 61 See Derrick Gingery, “Compounding Law: How Many “Outsourcing Facilities” Will Emerge?,” *The Pink Sheet* (Nov. 18, 2013).
- 62 “Compounding Questions Persist as Industry Enters Implementation Phase,” *Inside Health Policy* (Jan. 9, 2014).
- 63 Alaina Busch, “Compounding Questions Persist As Industry Enters Implementation Phase,” *FDA Week* (Jan. 10, 2014).
- 64 *Id.*
- 65 Alaina Busch, “FDA Press For Cooperation With Outsourcers Sparks Mixed Reaction,” *FDA Week* (Jan. 16, 2014).
- 66 See FDA, Registered Outsourcing Facilities, available at www.fda.gov/drugs/guidance/compliance/regulatoryinformation/pharmacy-compounding/ucm378645.htm.
- 67 See § 503B(d)(2).
- 68 FDA CPG, Section 460.200, *supra* 22 (listing “[c]ompounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products” as a factor the agency considered to determine whether to take enforcement action against a facility) (emphasis added).
- 69 Letter from Gail Costello, District Director, New England District Office, to Barry J. Cadden, NECC (Dec. 4, 2006).
- 70 *Id.*
- 71 *Id.*
- 72 Bronwyn Mixter and Dana A. Elfin, “Biosimilars Policy, Patents, Antitrust, Drug Compounding Among Year’s Key Topics,” *Bloomberg BNA Pharmaceutical Law & Industry Report* (Jan. 8, 2014).
- 73 Alaina Busch, “First DQSA Warning Letters Target Compounders Without Prescriptions,” *FDA WEEK* (Jan. 31, 2014).
- 74 The agency’s authority to collect these “user” fees appears in section 379h of the FDCA and is drafted to sunset after five years. See FDCA § 379h(b)(1). As a result, every five years Congress must re-enact this authority, and the need to do so always creates an opportunity for stakeholders to negotiate additional changes to the FDCA.

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