

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Honorable Marcia S. Krieger

Criminal Action No. 07-cr-00338-MSK

UNITED STATES OF AMERICA,

Plaintiff,

v.

THOMAS BADER, and
KEVIN HENRY,

Defendants.

**OPINION AND ORDER GRANTING, IN PART, MOTION FOR
RECONSIDERATION, AND RESERVING REMAINDER**

THIS MATTER comes before the Court pursuant to the Government's Motion for Reconsideration (# 410) of the Court's April 7, 2009 oral ruling (# 401), Defendant Bader's response (# 418), the Court's April 21, 2009 Order Directing Supplemental Briefing (# 424) on several issues, the Government's supplemental brief (# 426), Mr. Bader's supplemental brief (# 432), the Government's reply brief (# 440), Mr. Bader's reply brief (# 441), and an *amicus curiae* brief by the International Academy of Compounding Pharmacists and the American Pharmacists' Association¹ (# 445).

¹The American Pharmacists' Association has moved (# 456) to join in the International Academy of Compounding Pharmacists' *amicus* brief. That motion is granted and the American Pharmacists' Association prior motion for leave to file a separate *amicus* brief (# 442) is deemed withdrawn.

BACKGROUND

The Government commenced this criminal action against Mr. Bader and others on August 8, 2007. The allegations herein arise from Mr. Bader's actions, as a licensed pharmacist in the State of Colorado doing business through an entity named College Pharmacy, in which he filled prescriptions for patients whose doctors had instructed them to take human growth hormone ("HGH" or "sompatropin"). The current charging document, the Second Superseding Indictment (# 229), alleges 43 counts against Mr. Bader. Count 1, along with Counts 16 and 17, charge him with conspiracy to facilitate the sale of smuggled goods, 18 U.S.C. § 371, the "smuggled goods" being foreign-manufactured HGH – in violation of 18 U.S.C. § 371; Counts 2-11 charges him with mail fraud in violation of 18 U.S.C. § 1341, in that he made various false representations and omitted material information to patients about the HGH he was supplying them; Counts 13-15, along with Counts 21-43 charge him with distribution of HGH in violation of 21 U.S.C. § 333(e); and Counts 16 and 17 are not germane to the issues herein.

A. The Definitional Issue

As discussed in more detail below, the core issue in this case is whether the HGH imported by Mr. Bader was used by him as an ingredient in creating a "compounded"² drug that

² Ascertaining a precise legal definition of the term "compounding" is the focus of this Opinion. The Court provides the following generalized and colloquial definition of the term, solely for purposes of context for readers who may be unfamiliar with the notion of "compounding" as it is practiced in the pharmaceutical industry.

"Compounding" drugs involves a licensed pharmacist creating, from pharmaceutical ingredients, a specialized version of a particular drug in response to the specific needs of an individual patient. For example, if a patient requires drug X, but all available commercial formulations of drug X include, say, a coloring additive or binding agent that would cause allergies or other complications in the patient, a compounding pharmacist could assist the patient by creating, from scratch and using pharmaceutical ingredients, a customized version of drug X that lacked that additive or binding agent. Similarly, where a commercial drug is, say, only available in a pill form and the patient requires a liquid delivery, or where the commercial drug is available only in inappropriate dosage levels, a compounding pharmacist could create a unique version or dosage of the commercial drug that is more responsive to the patient's needs. The

Mr. Bader later distributed to patients, or whether Mr. Bader simply repackaged and passed along to customers what was in essence an already a finished, consumer-usable drug. The significance of this distinction between a “compounded” drug and a finished drug relates the degree of regulation by the Food and Drug Administration (“FDA”). As discussed in more detail below, the FDA rigorously regulates the importation and distribution of finished drugs that are ready for distribution to consumers, but exercises relatively little regulatory oversight over the importation of drug ingredients to be used by pharmacists to create “compounded” drugs and over the distribution of such “compounded” drugs to consumers. Whether Mr. Bader was engaged in the act of “compounding” the HGH before distributing it raises both legal and factual issues. The charges in this case (and the defenses thereto) are predicated on the degree to which the FDA exercises a regulatory role over the HGH at issue; that question, in turn, is informed by the disparity of treatment between FDA regulation of finished drugs versus “compounded” drugs. This, then, requires assessment raises a legal issue – namely, what constitutes “compounding”? – the answer to which ultimately affects whether the Government may proceed on the charges it has asserted against Mr. Bader. Ascertaining a legal definition of the term “compounding” is the subject of this opinion. The ultimate questions of what actions Mr. Bader performed and whether those actions meet the legal definition of “compounding” set forth herein are questions of fact that will eventually require resolution by a jury.

The parties have not stipulated to the underlying facts, but in consideration of whether, as a matter of law, the Government can proceed upon its charges, the Court assumes that it

practice of compounding has been a cornerstone of the practice of pharmacy for centuries, and many states require all of their licensed pharmacists to have training and skill in the practice of compounding.

would be able to establish the following³: Mr. Bader, and others, purchased HGH in bulk form from overseas suppliers. The bulk HGH shipments were routinely impounded by FDA inspectors at the border, who contacted Mr. Bader's agents for additional information about the shipments. In most circumstances, Mr. Bader's agents represented to the FDA inspectors that the HGH was being imported as an "active pharmaceutical ingredient" ("API") for use in drug compounding, rather than being a finished drug. This designation was important because importation of HGH as a finished drug was highly restricted, but to the extent that the HGH was an API, intended to be used by a pharmacist in the compounding of a finished drug, it was not subject to such restrictions. Relying on the agents' representations that the HGH was being imported as an API to be used on compounded preparations, the inspectors released the shipments for delivery to Mr. Bader at College Pharmacy.

When a customer of College Pharmacy presented a doctor's prescription for HGH, Mr. Bader inspected the bulk HGH powder he had received for quality and potency, measured out the proper amount of bulk HGH powder into a single-dose container, separately packaged an appropriate quantity of saline for the consumer to mix with the powder, labeled and packaged the HGH dosage and the saline together, and supplied the two items to the customer. (The customer was responsible for actually mixing the saline and HGH before administering the drug.)

The gravamen of the charges in the Second Superseding Indictment is that in this activity, Mr. Bader did not "compound" the HGH; he simply repackaged it. As a consequence, the Government contends that at the time of its importation and thereafter, the HGH was a finished drug rather than an ingredient in a compounded drug. Accordingly, the "smuggled

³The Court emphasizes that it is not making any factual findings regarding Mr. Bader's or others' conduct. Determination of the precise nature of the conduct that occurred will, of course, be a matter for the jury.

goods” counts are predicated on the assertion that Mr. Bader’s agents secured the release of the impounded HGH shipments by making false representations about Mr. Bader’s intentions (i.e. falsely stating he intended to treat the HGH as an API to be used in compounding, rather than admitting that he was simply going to repackage and distribute the finished drug), thus rendering the released bulk HGH a “smuggled” good. The mail fraud charges allege that Mr. Bader made misrepresentations and omissions to doctors and pharmacy customers about the HGH - e.g. falsely representing it as a “compounded drug,” and failing to correctly represent it as a finished drug that had not been approved by the FDA. The distribution charges entail the fairly straightforward accusation that Mr. Bader distributed finished HGH that had not been approved by the FDA.

B. The Procedural Context

As trial approached, it became clear to the Court that there was no immediately apparent legal definition of the act of “compounding” pharmaceutical ingredients. As a result, the Court invited (# 377) the parties to brief the issue prior to trial. Both sides responded with relatively concise briefs (# 383, 384). The Government primarily relied upon *Thompson v. Western States Medical Center*, 535 U.S. 357, 377 (2002), and its progeny. In *Western States*, the United States Supreme Court made reference to the notion that “compounding” involves “combin[ing], mix[ing], or alter[ing] ingredients.” Mr. Bader urged the Court to adopt an unspecified definition contained in the U.S. Pharmacopoeia (a practice manual used in the pharmacy industry), or, in the alternative, to adopt the definition provided under Colorado law at C.R.S. § 12-22-102(6), which deems compounding to include such acts as simply repackaging or relabeling a drug. By oral ruling on April 7, 2009 (# 401), the Court concluded that no federal law defined compounding and therefore Colorado law would apply. In reaching that decision, the Court rejected the reference in *Western States* as being dicta, found that the U.S.

Pharmacopoeia did not provide a workable definition of the term, and concluded that the FDA's traditional deference to state regulation of the practice of compounding warranted adopting a state law definition of that term.

The Government then filed the instant Motion for Reconsideration (# 410), supplying additional authority and arguing that the Court's adoption of the Colorado definition – one which deemed acts as minimal as repackaging or relabeling a drug to constitute “compounding” and leave the ensuing drugs effectively unregulated by the FDA – would be inconsistent with a definition of the term that the FDA has historically used, would be inconsistent with principles of statutory construction, would give undue effect to a state definition that was intended only to relate to issues of licensing, and would leave an unacceptable regulatory hole, among other things. If the Court nevertheless remained convinced that the Colorado definition was appropriate, the Government admitted that it would be unable to prove all but one of the HGH-related counts and requested that the Court dismiss those counts without prejudice.

Recognizing that the question of how to define the term “compounding” presented a more complex and nuanced question than the parties' initial briefing addressed, the Court directed (#424) supplemental briefing on the Government's Motion for Reconsideration. Specifically, the Court requested that the parties address the following issues: (i) whether the operation of the Food and Drug Administration Modernization Act (“FDAMA”), 21 U.S.C. § 353a, is essential to the consideration of the charges in this case; (ii) assuming the operation of FDAMA is essential to the case, whether this Court would be required to address an issue as to the constitutionality of the act upon which other Circuit Courts have split; (iii) whether there was additional authority to consider in addressing what the appropriate definition of “compounding”; (iv) whether the absence of a meaningful definition of the term “compounding” would affect the constitutionality of FDAMA and the Government's ability to bring the charges here; and (v) if a

definition of “compounding” could be ascertained, which party would have the burden of proving that the drugs at issue in this case were/were not “compounded.” The Court has considered the supplemental briefs filed by the parties (# 430, 432), the parties’ responses to each other’s supplemental brief (# 440, 441), and an *amicus* brief filed by two pharmacy industry groups (# 445).

ANALYSIS

A. Historical context of FDAMA

A full understanding of the issues presented here requires some appreciation of the historical context of FDA regulation as it relates to “compounded” drugs. Comprehensive federal regulation of pharmaceuticals began in 1938, with the passage of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* As relevant here, the FDCA purported to regulate all “new drugs.” A new drug is defined as “any drug . . . the composition of which is such that such drug is not generally recognized [among experts] as safe and effective for use under the conditions prescribed.” 21 U.S.C. § 301(p). Pursuant to 21 U.S.C. § 355(a), any new drug must have undergo “new drug approval” (“NDA”) by the FDA before the drug can be sold in interstate commerce. That statute goes on to describe the manner in which NDA is obtained, but it is sufficient to note for purposes of this ruling that the NDA process can be extensive and prolonged.

The effect that the FDCA had on the traditional practice of compounding drugs remains a subject of significant debate. Compounded drugs, which are typically created on an *ad hoc* basis and in limited quantities for particular patients at the request of a treating physician, are not particularly susceptible to individualized regulation under the NDA paradigm. Simply put, it would be impractical for a pharmacy to have to go through the extensive NDA process each and every time a patient needed a particular drug compounded in a particular way. *See generally*

Medical Center Pharmacy v. Mukasey, 536 F.3d 383, 398 & n. 31, 32 (5th Cir. 2008) (discussing the unsuitability of the NDA process for compounded drugs). However, practicality aside, the FDCA contains no exception to the definition of a new drug for one that is compounded. Thus, on its face, the FDCA is susceptible to an interpretation that would require all compounded drugs to go through the NDA process. *Id.* at 397.

For half a century, practicality prevailed – the FDA simply declined to exercise any authority it might have exerted over compounded drugs, electing to defer to the state regulation of pharmacists who engaged in the practice of compounding. *Western States*, 535 U.S. at 362. However, in the 1990's, the FDA became increasingly concerned about pharmacies that “compounded” large batches of drugs for widespread, interstate sale. The FDA believed that these pharmacies were exploiting a loophole in the regulatory scheme, using the lack of federal regulatory oversight of compounded drugs to evade the NDA process, allowing the pharmacists a competitive advantage over manufacturers of similar drug products. *See e.g. Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 (5th Cir. 1995); *U.S. v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1402-06 (7th Cir. 1990) (describing one such operation drawing the attention of the FDA).

The FDA first attempted to deal with this “compounding loophole” in 1992. The FDA issued Compliance Policy Guide (“CPG”) 7132.16, a document intended to provide advice to FDA employees and industry practitioners about FDA policies. *Patients for Customized Care*, 56 F.3d at 596. Because the 1992 CPG was effectively superseded prior to the events at issue here, it is not necessary for the Court to set forth the terms of that document in detail. It is sufficient to observe that the 1992 CPG iterated the FDA’s continued intention to permit pharmacies to “extemporaneously compound[] reasonable quantities of human drugs upon receipt of a valid prescription,” subject only to the regulation and control of state authorities.

But the CPG noted that the FDA would “exercise its enforcement discretion” if it concluded that the actions of a pharmacy nominally engaged in compounding drugs “raises the kind of concerns normally associated with a manufacturer.” *Patients for Customized Care*, 56 F.3d at 594. The CPG went on to list nine factors that would be considered by the FDA in determining whether a pharmacy’s conduct constituted “traditional compounding” or “manufacturing.” Among those factors were: (i) that the drugs were compounded in significant amounts before a prescription was received; (ii) the APIs used in the compounding were not from FDA-registered suppliers; (iii) the products were being distributed to third parties for resale to customers, rather than to customers themselves; and (iv) the compounded products were essentially copies of commercially-available products.

In 1997, Congress incorporated many of the provisions of the 1992 CPG into formal legislation in the form of FDAMA, 21 U.S.C. § 353a. That statute expressly provides that certain portions of the FDCA – including the NDA provisions of § 355 – “shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order . . . [and] if the drug product meets the requirements of this section.” 21 U.S.C. § 353a(a). Thus, under FDAMA, a “compounded” drug is exempt from the NDA approval process if: (i) it is compounded by a licensed pharmacist pursuant to a valid prescription issued to an individual patient (or is prepared in limited quantities in anticipation of receiving a prescription based on prior business history), 21 U.S.C. § 353(a)(1), (2); (ii) the APIs and compounding techniques used comply with industry standards set forth in the U.S. Pharmacopeia or other sources, 21 U.S.C. § 353a(b)(1)(A), (B); (iii) the compounded drug is not one that appears on an FDA list of specific drugs deemed to be unsafe, 21 U.S.C. § 353a(b)(1)(C); (iv) the compounding does not produce “inordinate amounts” of a drug that is “essentially [a copy] of a commercially available drug product,” 21 U.S.C. §

353a(b)(1)(D); (v) the drug is not one that the FDA has specifically designated as being unsuitable for compounding, 21 U.S.C. § 353a(b)(3)(A); (vi) conditions are met that ensure that the pharmacy is not producing “inordinate amounts of compounded drug products,”⁴ 21 U.S.C. § 353a(b)(3)(B); and (vii) the pharmacy must refrain from advertising or promoting the compounding of any particular drug or class of drugs, 21 U.S.C. § 353a(c).⁵

Shortly after FDAMA’s enactment, a number of pharmacists brought a First Amendment challenge against the portion of FDAMA that prohibited compounding pharmacies from advertising or promoting certain compounded drugs. In *Western States Medical Center v. Shalala*, 238 F.3d 1090 (9th Cir. 2001), the Ninth Circuit found that the advertising restrictions violated the First Amendment, concluding both that the provision failed to advance the Government’s purported justifications and further, that less-restrictive alternatives could adequately serve the Government’s stated interests. *Id.* at 1093-96. That Court went on to find that the constitutionally-impermissible restriction on advertising was not severable from the remainder of FDAMA, and determined that the entire act was unconstitutional. *Id.* at 1096-98.

The Supreme Court affirmed the Ninth Circuit’s decision in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) (hereafter “*Western States*”), agreeing that the advertising restriction unconstitutionally abridged pharmacists’ freedom to engage in commercial speech. *Id.* at 366-77. However, the Court expressly noted that the issues presented for review did not

⁴Specifically, the pharmacy must be in a state that has entered into a “memorandum of understanding” with the FDA concerning interstate distribution of “inordinate amounts of compounded drug products,” or, in the alternative, interstate sales of compounded drugs must constitute 5% or less of the total number of prescriptions filled by the pharmacy.

⁵FDAMA does contain a provision entitled “‘Compounding’ defined,” but that definition operates by exclusion, stating that the term “‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer.” 21 U.S.C. § 353a(f). That definition does not appear to be of significance here.

extend to the Ninth Circuit's ruling on severability, and the Court declined to address that question. *Id.* at 360. Thus, the effect of *Western States* was to affirm the conclusion that the advertising restriction in FDAMA was unconstitutional nationwide, and by operation of the Ninth Circuit ruling, FDAMA was deemed to be void in its entirety (at least in the Ninth Circuit).

In response to *Western States*, the FDA quickly returned to the 1992 CPG, revising it to reflect the change in the legal landscape. In 2002, it issued CPG 460.200⁶ that states that “the FDA is considering the implications of [*Western States*] and determining how it intends to regulate pharmacy compounding in the long term.” The 2002 CPG was intended to detail the FDA's position with regard to regulatory enforcement against compounding pharmacists until a more formal statement of FDA policy was delivered. (The parties agree that, notwithstanding the language in the 2002 CPG, no revised policy statement has yet been issued.)

In most material respects, the 2002 CPG was identical to the 1992 CPG. However, after summarizing the history described above, the 2002 CPG's “Background” section concludes with the statement that due to the Ninth Circuit's ruling, “all of [*i.e.* FDAMA] is now invalid.” The 2002 CPG goes on to “issue guidance to the compounding industry on what factors the Agency will consider in exercising its enforcement discretion regarding pharmacy compounding.” It emphasizes that the FDA will continue defer to state regulation of the traditional practice of compounding, but notes that “when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer,” the FDA will consider taking regulatory action. It recited the same nine factors found in the 1992 CPG, stating that the FDA will consider these factors in determining whether the pharmacy's actions constitute the

⁶www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm

traditional practice of compounding or manufacturing. *Id.*; *Wedgewood Village Pharmacy, Inc. v. U.S.*, 421 F.3d 263, 272 n. 11 (3d Cir. 2005) (quoting the nine factors).

As relevant to the issues herein, the legal landscape regarding compounded drugs remained unchanged from the 2002 CPG until 2006. In *Medical Center Pharmacy v. Gonzales*, 451 F.Supp.2d 854 (W.D. Tx. 2006), a number of compounding pharmacies, including Mr. Bader's College Pharmacy, sought a judgment declaring, among other things, the FDA lacked the authority to regulate compounded drugs because they do not fall within the "new drug" definition of the FDCA. *Id.* at 856-57. Noting that it was not bound by the Ninth Circuit's declaration that FDAMA was unconstitutional in its entirety, the trial court observed that FDAMA "exempted compounded drugs from the FDA's drug approval process." *Id.* at 861-62. Concluding that it had to independently assess the question of whether FDAMA's non-advertising provisions were severable, the court found that the unconstitutional advertising restriction was severable from the remainder of FDAMA, allowing the remainder of the statute to remain in effect. Turning to the question of what effect the viable portions of FDAMA had on the FDA's ability to regulate compounded drugs under the "new drug" provisions of the FDCA, the court explained that "Congress intended to declare that compounding is an approved and legal practice," and concluded that "any drugs created by the compounding process are authorized under [FDAMA] and are therefore implicitly exempt from the new drug approval process." *Id.* at 863. The court noted, however, that "the exemption for compounded drugs from the new drug definition is limited to compounds which are made in reasonable quantities upon receipt of a valid prescription for an individual patient from a licensed practitioner[; d]rugs that are compounded in large quantities before a prescription is received from a doctor do not fall within the narrow exemption this Court finds exists." *Id.* Thus, for all practical purposes, the trial court's ruling was that those drugs that were both: (i) compounded, and (ii) otherwise in

compliance with the provisions of the now-reanimated FDAMA, were not subject to the NDA process.

The Government appealed that decision to the Fifth Circuit Court of Appeals. In *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008) (“*Medical Center*”), the Fifth Circuit agreed that the unconstitutional advertising restrictions in FDAMA were severable, thereby allowing the remainder of the act to be effective. *Id.* at 401-06. However, it reversed the trial court’s blanket conclusion that compounded drugs (that otherwise complied with FDAMA) were exempt from FDA regulation. Instead, the Fifth Circuit explained that such drugs are “neither uniformly exempt from the new drug approval requirements nor uniformly subject to them. Properly construed, [the FDCA and FDAMA] create[] a limited exemption from the new drug approval requirements for compounded drugs that comply with the conditions explicitly delineated in FDAMA.” *Id.* at 394 (emphasis in original). Although nominally a reversal of the trial court based upon a more nuanced analysis, the practical effect of the Fifth Circuit’s conclusion is the same as that reached by the trial court: (i) FDAMA (other than the advertising restriction) remains viable in the Fifth Circuit (and, logically, in any jurisdiction outside the Ninth Circuit that finds it sufficiently persuasive on that point); and (ii) compounded drugs that comply with the terms of FDAMA enjoy an exemption from NDA requirements.

With this history in mind, the Court turns to the specific questions posed to the parties.

B. Whether consideration of FDAMA is essential to this action

The first question posed by the Court was whether the operation of the provisions of FDAMA is essential to the consideration of the charges against Mr. Bader. The Government takes the position that Mr. Bader’s HGH was imported, repackaged, and distributed by Mr. Bader to customers in an essentially unchanged, finished form. As such, the Government contends that it was a “new drug” under the FDCA, subject to NDA requirements and the

penalties that accompany failure to comply with such requirements. The Government's position is that FDAMA is not germane to its view of the events, but concedes that the statute would supply Mr. Bader with a potential affirmative defense – that the drug was “compounded” and thus statutorily exempt from the NDA process – should he choose to invoke it. (The necessarily implication from the Government's position is that, because Mr. Bader has no valid defense without FDAMA, the statute is essential to Mr. Bader and he will be forced to invoke it.)

Mr. Bader's contention is also that FDAMA is irrelevant, but he reaches that conclusion from a different chain of reasoning. He notes that the conduct at issue here occurred post-*Western States* and pre-*Medical Center* – that is, a time when it appeared to all involved that FDAMA was void in its entirety. Thus, he contends that because even the FDA considered FDAMA to be invalid during the time frame at issue here, it would be improper for the Court to attempt to apply it. Furthermore, he argues that he does not need FDAMA to create a defense for him, as he was entitled to rely on the trial court's ruling in *Medical Center*, which he construes as standing for the proposition that compounded drugs are categorically exempt from the NDA requirements.⁷

The conduct alleged in the Second Superseding Indictment occurred over the period from roughly April 2004 to June 2007. During that period of time, the confluence of the Supreme Court and Ninth Circuit decisions in the *Western States* case had rendered FDAMA entirely void, at least within the Ninth Circuit. Mr. Bader and the *amici* contend that the FDA thereafter conceded the position that FDAMA was void nationwide, and there is at least some indication in the public 2002 CPG that the FDA informed the public that it intended to proceed as if FDAMA

⁷A necessary factual premise in Mr. Bader's argument is that his HGH was indeed “compounded”, which circles back to the definition of compounding.

was void in its entirety. CPG 460.200, *supra*. (“Accordingly, all of [FDAMA] is now invalid”).

Because the FDA considered FDAMA to be void during the timeframe of the conduct at issue, Mr. Bader argues that it would be improper to apply the statute in this case. Assuming, without necessarily finding, that the FDA’s own view of the status of FDAMA is dispositive of the question of whether FDAMA applies, the 2002 CPG is significant evidence that FDAMA should not be given effect here. However, like the phoenix rising from its own ashes, the death of FDAMA gave rise to a new regulatory paradigm, the 2002 CPG. Any pharmacist who relied upon the 2002 CPG as proof that the FDA was laying FDAMA to rest was simultaneously put on notice that the FDA nevertheless intended to continue to administratively exercise enforcement discretion very similar to that previously reflected in statute. There are minor differences in wording between FDAMA and the 2002 CPG which give rise to slightly different obligations, but the ultimate thrust of both pronouncements are the same: drugs produced by “traditional compounding” are of little concern to the FDA, but if compounding starts to resemble “manufacturing” – *i.e.* when certain specific factors are present – the FDA will require the resultant compounded drugs to undergo the NDA process. Both documents describe a “safe harbor” to which compounding pharmacists can conform their conduct in order to avoid NDA requirements attaching to their products.

Mr. Bader argues that he needs no safe harbor because the trial court in *Medical Center* ruled that the FDA to had no authority to regulate compounded drugs in any capacity. He further argues that because both the Government (through the FDA) and he (through College Pharmacy) were parties to that action, the decision should be given preclusive effect here. This argument is misplaced for several reasons. First, the trial court’s ruling was in 2006, and even assuming it could justify Mr. Bader’s conduct after August 30, 2006 (the date of the trial court’s decision), the ruling provides him no shelter for conduct occurring prior to that date. Many of the

allegations in the Second Superseding Indictment predate such ruling.

Second, and more importantly, the argument misreads the actual holding of the trial court. The trial court's ruling in *Medical Center* was expressly premised upon the court's finding that the non-advertising provisions of FDAMA were severable, and thus remained effective:

the remaining [severable] provisions of [FDAMA] demonstrate that Congress intended to declare that compounding is an approved and legal practice. The existence of the remaining portions of the statute permit pharmacies to compound drugs. Because pharmacies are permitted to compound, this Court finds that any drugs created by the compounding process are authorized under [FDAMA] and are therefore implicitly exempt from the new drug approval process. . . .

451 F.Supp.2d at 863 (emphasis added). Mr. Bader may wish that the court had concluded that the FDCA's "new drug" definition did not apply to compounded drugs under any circumstance, but it is clear that the trial court concluded that only those compounded drugs that complied with the safe harbor language of FDAMA avoided the NDA process. *Id.* ("[d]rugs that are compounded in large quantities before a prescription is received from a doctor do not fall within the narrow exemption this Court finds exists") (emphasis added). Thus, contrary to Mr. Bader's argument that the trial court's decision stands for the proposition that "regardless of the status of FDAMA, . . . compounded drugs were not new drugs," this Court understands the trial court's decision in *Medical Center* to be more limited - that only drugs compounded in compliance with the restrictions set forth in FDAMA fall outside FDA regulation and the NDA process.⁸

⁸Assuming that the trial court's decision in *Medical Center* swept as broadly as Mr. Bader contends, there remains the question of how that ruling applies to the conduct at issue here in light of the 5th Circuit's subsequent reversal. Although Mr. Bader has cited to some authority loosely standing for the proposition that charges of criminal conduct are assessed in the light of the law that existed at the time, there remains an unsettled question of the extent to which he would be permitted to rely on the trial court's opinion in *Medical Center* while the appeal of that decision was pending before the 5th Circuit. The parties were not asked to brief the question of

Because the trial court opinion in *Medical Center* does not sweep as broadly as Mr. Bader contends, the Court concludes that the law in effect at the time of the conduct herein exempted compounded drugs from the NDA process only when those drugs were both: (i) compounded, and (ii) created within the limitations contained in FDAMA/the 2002 CPG.⁹ The second prong of that test makes clear that Mr. Bader's conduct must comply with the safe harbor provisions of FDAMA/the 2002 CPG in order to avoid FDA regulation through the NDA process. Accordingly, either FDAMA or the 2002 CPG¹⁰ are essential to the definition of whether a practice constitutes compounding. Only those compounded drugs that fall within the specific provisions of FDAMA or the 2002 CPG are exempt from the NDA regulation process.

C. Whether FDAMA's provisions are severable

Mr. Bader's initial position is that because he does not consider it appropriate for the

when a criminal defendant is entitled to rely upon a court ruling that is undergoing a pending appeal, and the Court confesses that its research reveals no clear answer on that point. Nevertheless, in light of its analysis here, the Court need not attempt to resolve this issue.

⁹Mr. Bader extensively argues that both legislative history from negotiations over FDAMA and a 1989 "smoking gun memo" from the FDA support the proposition that the FDA never had any power to regulate compounded drugs, whether "traditionally compounded" or "manufactured." This evidence might be fascinating to a legal historian attempting to answer the question of whether such power existed prior to FDAMA, but they are not persuasive in the post-FDAMA context. Notwithstanding any uncertainty it may have harbored in 1989, the 1992 CPG clearly advised the public that the FDA believed it had the authority to exert regulatory power over certain compounded drugs. Any lingering doubts on that question were resolved in 1997 by the passage of FDAMA, whose very operation implicitly affirms the notion that the FDA possesses the power to regulate compounded drugs; no FDAMA-described safe harbor would have been necessary if the FDA indeed lacked the power to regulate compounded drugs. *See e.g. Medical Center*, 536 F.3d at 400 ("with only the original FDCA's text . . . and uncertain evidence of congressional intent, this might have been a difficult [issue]. A subsequent amendment to the FDCA [*i.e.* FDAMA] however, makes it easy").

¹⁰Because the provisions of FDAMA and the 2002 CPG are so similar, it is not essential at this time for the Court to conclusively determine which one actually applied to the conduct at issue here. The Court is confident that resolution of that question one way or the other will have only imperceptible effects on how the jury is instructed, and indeed, anticipates that the question is so insignificant in its effect that the parties may be able to reach an agreement as to which document's terms control.

Court to apply the terms of FDAMA to this case, it is unnecessary for the Court to reach the question of whether the unconstitutional advertising restriction is severable from the rest of FDAMA. However, he offers an alternative argument on the substantive issue, asserting that *Medical Center* provides the proper analysis and conclusion on the issue of severability. Thus, the Court understands that him to contend that the advertising restriction is severable and that the remainder of FDAMA retains constitutionally viable.

As can be expected when faced with an unresolved circuit split, the Government's position on this question is stated with a degree of nuance: it asserts that the FDA deems the *Medical Center* analysis – that FDAMA is severable and largely viable – to apply to pharmacies operating in the Fifth Circuit, as well as those pharmacies outside the Fifth Circuit that were nevertheless parties to the *Medical Center* case.¹¹ Because Mr. Bader was one of those parties, the Court understands the Government's position here to be that FDAMA is severable. Thus, the parties are in agreement on this point, and the Court sees nothing in the *Medical Center* decision that is so palpably incorrect that applying its rule would clearly be error. Accordingly, to the extent it is necessary for the Court to reach the severability question in this case, it would adopt the *Medical Center* analysis and conclude that the non-advertising portions of FDAMA are viable.

D. Definition of “compounding”

Thus, at long last, the analysis reaches the pivotal question of whether, under federal law, there is a controlling definition of the term “compounding.” To sharpen the dispute somewhat, the Court notes that the Government contends that Mr. Bader's actions were not “compounding”

¹¹As to all other pharmacies, the FDA's position is that the 2002 CPG controls.

because they were little more the simple “repackaging” of the bulk HGH.¹² Thus, the fundamental question is whether the definition of the term “compounding,” as that term is used in either FDAMA or the 2002 CPG, sufficiently encompasses actions as simple as mere “repackaging” of bulk HGH.

In consideration of the initial submissions by the parties on this question, the Court concluded that federal law did not define compounding and therefore concluded that state law – in this case, C.R.S. § 12-22-102(6) – provided the appropriate definition of the term. Compounding, under Colorado law, includes “[re]packaging” of a drug product. C.R.S. § 12-22-102(6) The Government argues that this conclusion is in error, and that a definition that deems “compounding” to occur only when a pharmacist actually mixes or combines multiple ingredients to create a finished drug is more appropriate. Using its preferred definition, the Government reasons that Mr. Bader’s mere repackaging an otherwise finished drug does not constitute “compounding.”

The Court will not restate its prior reasoning rejecting the Government’s contention that rejected any purported definition contained in *Western States*. The Court also finds that the Government’s supplemental arguments in favor of its preferred definition without merit. It is undisputed that Congress could have, but did not ever affirmatively define the term “compounding.” Neither the FDCA nor FDAMA purport to contain an affirmative definition of the term “compounding.” Indeed, the Government points to no particular evidence suggesting that Congress even entertained a specific understanding of the meaning of that term. Nor does it appear that the FDA adopted a formal definition for purposes of enforcement. The 1992 CPG,

¹²Once again, the Court emphasizes that it makes no factual findings in this Order. The Court is cognizant that in this discussion, it often oversimplifies the parties’ positions, but it does so knowingly, and for the purpose of highlighting the fundamental aspect of the dispute.

the forefather of FDAMA, contained none. The best that can be said is that the 1992 CPG, like FDAMA, defined the term only by negative implication, identifying those acts that were not consistent with the notion of “compounding.” Unfortunately, none of the specifically-identified acts shed light on the key issue here: whether simply repackaging a drug constitutes “compounding.”

The Government’s supplemental briefing raises two additional major arguments in favor of its definition of “compounding”: (i) “compounding” is a “term of art,” having a clear and uniform meaning understood both by the FDA (as embodied in certain FDA publications dating back to 2003, as well as in 20 “warning letters” sent by the FDA to compounding pharmacies between March 2006 and December 2008) and those in the pharmacy industry, and that the Court can assume that Congress intended to adopt that settled definition; and (ii) that the term “compounding” has a “common and ordinary meaning,” ascertainable from dictionaries, and that Congress intended to adopt that common meaning. The Court has carefully considered these arguments, but finds them to be without merit for two reasons. First, it is incumbent upon Congress to state its understanding of the terms it uses and improper for a court to speculate as to its intentions, especially where there is none evident in the legislative history and Congress as well as the FDA deferred to the states in regulation of the practice. Second, as is highlighted by the *amici*, the contention that there is a universally-understood definition of compounding within the industry, is belied by the fact that states have promulgated varying definitions. For example, Alabama defines “compounding” in the conjunctive, apparently requiring a pharmacist to “prepar[e], mix[], assembl[e], package[], and label[] a drug.” Ala. Code § 34-23-150(3) (emphasis added); *see also* Oh. Rev. Code § 4729.01(C). Other states, including Colorado, use a similar definition phrased disjunctively, apparently deeming a pharmacy to be “compounding” any time it performs any of the listed acts (*e.g.* when merely repackaging). C.R.S. § 12-22-

102(6); *see also* Ak. Stat. § 08.08.480(3); Ga. Code § 26-4-5(4); Mt. Stat. § 37-7-101(7); N.D. Stat. § 43-15-01(24). Kentucky uses an entirely different definition - “compounding” is the “the preparation or labeling of a drug,” which, in turn, can include simple repackaging or reconstitution of a finished drug. K.R.S. § 315.010(5). Simply put, in many states, a pharmacist who simply repackages or relabels a drug is engaged in the act of “compounding.” The variances among definitions stand in sharp contrast to the Government’s contention that there is a single, commonly-accepted industry or common definition of the term “compounding,” and even more forcefully refutes the contention that any commonly-accepted definition necessarily excludes simple repackaging.¹³

Recognition of state-law definitions of the term “compounding” is entirely consistent with the FDA’s decades-long practice of deferring to state regulation of compounded drugs. Indeed, even when the FDA became concerned in the 1990s that some pharmacies were abusing the compounding loophole, the FDA did not attempt to close that loophole in part by promulgating a definition of “compounding” to prevent pharmacies in Alaska, Colorado, Kentucky, and elsewhere from merely repackaging finished drugs and calling it “compounding.”. To the contrary, the 1992 CPG expressly noted the FDA’s intention to continue the practice of deferring to the states to define and regulate the compounding of drugs,

¹³The Court is also unpersuaded that the FDA materials cited by the Government reflect a purposeful regulatory definition of the term “compounding.” The various FDA surveys cited in the Government’s brief do contain the language quoted by the Government, but in a context that is not particularly apropos of the remainder of the document and does not purport to be setting forth a definition intended to guide pharmacies in conforming their behavior. The warning letters issued by the FDA specifically cite *Western States* as the authority for its definition of the term, a citation this Court has already found to be dicta. Moreover, to the extent that these documents can be said to reflect a consistent FDA interpretation of the term “compounding,” the Court notes that these documents all post-date *Western States*, suggesting that the FDA, like the Government here, has attributed more weight to the “definition” in that case than such dicta can bear.

and purported to flex the FDA's regulatory muscle only in specifically-defined category of situations in which the compounding in question carried certain specific indicia of "manufacturing." Similarly, FDAMA underscores the FDA's willingness to continue to allow states to take the lead role in regulating drug compounding. *See e.g.* 21 U.S.C. § 353a(3)(B)(i) (allowing states to enter into a "memorandum of understanding" in which the state, not the FDA, will be responsible to investigate complaints of excessive interstate shipments of purportedly "compounded" drugs). The FDA's longstanding policy of deferring to state regulation of compounded drugs – a history reaffirmed by the FDA in the 1992 and 2002 CPGs and by Congress in FDAMA – strongly suggests that state law is the appropriate place to look for a legal definition of the term "compounding" as used in FDAMA.

Accordingly, the Court, having reconsidered the issue in light of the parties' supplemental briefing, nevertheless concludes that the appropriate definition of "compounding" remains that provided by C.R.S. § 12-22-102(6).¹⁴

That is not the end of the inquiry, however. Although the FDA may have deferred wholesale to state regulation of compounded drugs for half a century, it is clear that the FDA began to chip away the edges of that deference by the 1990s. The 1992 CPG, FDAMA, and the 2002 CPG all make clear that the FDA is content to allow "traditional compounding" to remain

¹⁴The Court acknowledges that deference to state definitions of the term theoretically result in awkward situations. It results in a patchwork regulatory framework, where acts in one state might constitute "compounding" and thus likely be exempt from FDA scrutiny, while those same acts would not enjoy such deference in another state. Moreover, the Court acknowledges the Government's concern that some states define the term so broadly that nearly every action by a pharmacist constitutes "compounding," removing nearly all federal regulatory oversight from the commercial drug distribution process. But these effects are the direct result of the FDA's decision to defer to state regulation of drug compounding. Leaving a matter to the states for regulation invariably will result in a variety of different regulatory approaches with varying degrees of strictness. In any event, the most egregious forms of abuse contemplated by the Government can be prevented by the FDA simply by invoking the terms of the CPG/FDAMA as discussed *infra*.

the subject of state regulation, but that the FDA intends to regulate “manufacturing” conducted under the guise of compounding. There is no reason why the state definition of “compounding” and the CPG/FDAMA definition of circumstances that subject even “compounded” drugs to federal regulation cannot simultaneously co-exist. The CPG/FDAMA specifically define those circumstances in which a pharmacy may be nominally complying with state laws governing compounding but has nevertheless crossed over into the realm of “manufacturing,” thus warranting FDA scrutiny.

In other words, the CPG/FDAMA operates as a limited revocation of the FDA’s deference to state regulation of “compounded” drugs. Those drugs which are “compounded” under state law nevertheless may be regulated if they fall within one or more of the criteria set forth in the CPG/FDAMA. In such event, although they are “compounded” (but not “traditionally compounded”), they nevertheless also bear indicia of “manufacturing” that is clearly within the bailiwick of FDA regulation. As a consequence, they lose the exemption from the NDA process that “traditionally compounded” drugs enjoy. *Accord Medical Center*, 536 F.3d at 405. Although the precise contours of the boundary between “traditional compounding” and “manufacturing” are slightly different, depending on whether the controlling enactment is FDAMA or the CPG, Mr. Bader has long been on notice of the criteria by which the FDA would determine whether a nominally “compounded” drug would cross that boundary and the consequences (i.e. loss of the NDA exemption) that will flow from crossing that line.

Thus, with regard to the question of compounding, the jury will be instructed in two phases: (i) that “compounding” is defined according to the terms of Colorado law as set forth in C.R.S. § 12-22-102(6); and (ii) that a drug that is otherwise “compounded” according to that definition may still be subject to NDA requirements and other regulatory burdens if it runs afoul of the terms of the CPG/FDAMA (whichever the Court ultimately concludes in applicable).

Because the Colorado definition of “compounding” is so broad, it is likely that Mr. Bader may succeed on the first prong. But if the evidence establishes that in the course of compounding the HGH (under the Colorado definition), Mr. Bader used unapproved APIs, or compounded inordinate amounts of drug products that were copies of a commercially-available product, or otherwise strayed into one of the categories of prohibited activity specified in the CPG/FDAMA, the jury may find that he crossed the line from “traditional compounding” to “manufacturing” under federal law. In that circumstance, they may find that he was subject to the NDA process and various other aspects of FDA regulation.

The Government identified those claims that would be affected if the Court concluded that “compounding” was defined by state law, but that identification was apparently based on the conclusion that the definitional question was a binary one. Where both the state definition of “compounding” and the provisions of the CPG/FDAMA can apply simultaneously, the Government’s position may be different. Indeed, the Government’s response (# 440) to Mr. Bader’s supplemental brief suggests that it believes it can prove that even if Mr. Bader was “compounding” under Colorado law, his actions are not exempt from FDA regulation because he was simultaneously violating the provisions of the CPG/FDAMA. *Docket # 440 at 2* (suggesting it can prove that Mr. Bader’s compounding activities were not undertaken pursuant to a valid prescription, and thus, ran afoul of 21 U.S.C. § 353a(a)(1), and that Mr. Bader was regularly compounding a drug that was a copy of a commercially-available HGH product, thus violating 21 U.S.C. § 353a(b)(1)(D)). Accordingly, the Court will not simply assume that its (re-)adoption of the Colorado definition of “compounding” compels dismissal of any Counts at this time. Rather, the Court will conduct a hearing on **July 31, 2009 at 8:30 a.m.**, where the parties will address the consequences of this ruling on the counts in the Second Superseding Indictment.

E. Effect of an inadequate definition

Because the Court has concluded that there is an adequate definition for the term “compounding,” it does not reach the parties’ arguments as to the consequences that would flow from such a term being undefined. The Court concludes that both FDAMA and the 2002 CPG put Mr. Bader on sufficient notice that certain types of compounded drugs could nevertheless be subject to NDA requirements and FDA regulation.

F. Burden of proof on issue of “compounding”

The final issue on which the Court requested supplemental briefing was which party would bear the burden of proving that the drugs in question were or were not “compounded.” Both the Government and Mr. Bader agree that, to the extent the operation of FDAMA is germane to this action, it operates as an affirmative defense on which Mr. Bader will bear the burden of proof by a preponderance of the evidence. Thus, if the Government carries its burden of showing that the drugs distributed by Mr. Bader fall within the FDCA’s “new drug” definition and NDA requirements, the burden will shift to Mr. Bader to establish his affirmative defense: that the drugs were “compounded” as that term is defined in Colorado law and, further, that such compounding took place within the boundaries established by the CPG/FDAMA – *e.g.* in response to a valid prescription (or in reasonable anticipation of future prescriptions), using approved ingredients, not regularly copying a commercially-available product, etc.

CONCLUSION

For the foregoing reasons, the Government’s Motion for Reconsideration (# 410) is **GRANTED IN PART**. Upon reconsideration, the Court modifies its April 7, 2009 oral ruling as follows: the term “compounding,” as used in FDAMA, is defined by state law – in this case, C.R.S. § 12-22-102(6). However, because the parties agree that the non-advertising provisions of FDAMA are severable and constitutional, FDAMA operates as a limited revocation of the FDA’s deference to state regulation of compounded drugs, such that any otherwise

“compounded” drug that fails to meet the requirements of FDAMA is subject to FDA regulation, including NDA requirements. The parties agree that Mr. Bader will have the burden of proof at trial to show both that his actions constituted “compounding” under state law and that his conduct does not violate the terms of FDAMA. The motion is **DENIED IN PART**, insofar as the Court **RESERVES RULING** on that portion that requests dismissal of some of the charges in light of this definition. The Court will conduct a hearing on **July 31, 2009** at **8:30 a.m.**, at which the parties shall be prepared to address which claims, if any, are affected by this ruling. The American Pharmacists’ Association Motion to Join (# **456**) in the previously filed *amicus* brief is **GRANTED**, and the American Pharmacists’ Association prior Motion for Leave to File an *amicus* brief (# **442**) is deemed **WITHDRAWN**.

Dated this 23d day of July, 2009

BY THE COURT:



Marcia S. Krieger
United States District Judge