IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA	::	
	::	
v.	::	**CRIMINAL ACTION FILE**
	::	**NO. 1:17-cr-229-AT-CMS**
JARED WHEAT,	::	**(First Superseding)**
JOHN BRANDON SCHOPP, and	::	
HI-TECH PHARMACEUTICALS, INC.	::	**[Magistrate Judge Baverman]**
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O R D E R

Defendants appeared before me on October 4, 2017 for their initial appearances on the first superseding indictment, [Doc. 7]. They were released on conditions, with each agreeing, among other things, to not, directly or indirectly through third parties, manufacture, distribute or sell adulterated foods or misbranded drugs, including but not limited to products containing 1, 3 Dimethylamylamine ("DMAA") or its chemical equivalent, and which prohibitions included not purchasing or receiving DMAA ingredients; or manufacturing, processing, packaging, marketing, or distributing food or dietary supplement products containing DMAA or its chemical equivalent. [*See* Doc. 19 (Hi-Tech); Doc. 22 at 2, 4 (Wheat); Doc. 26 at 2, 4 (Schopp)]. They now move to amend the conditions of release to remove this condition. [Docs. 45 (Wheat, Hi-Tech), 56 (Schopp motion to adopt)]. At a hearing on December 7, 2017,

I orally granted Schopp's motion to adopt Document 45 and heard arguments from counsel. For the following reasons, the motion to amend the conditions of release (as to the individual defendants) and order (as to Hi-Tech) is **DENIED**.

Wheat, on behalf of himself and Hi-Tech, contend that the DMAA prohibitions should be removed from the conditions of release (or that the order concerning Hi-Tech should be vacated) because (1) the DMAA restrictions amount to an improper attempt by the Government to obtain what Defendants claim the Government either failed to seek or failed to obtain in separate civil and/or administrative proceedings, and (2) the Government is improperly using these criminal proceedings to gain an advantage in related civil proceedings. [Doc. 45 at 28-34]. Additionally, Wheat argues that he entered into the agreement with the Government on his own behalf and that of Hi-Tech under duress, because he agreed to the conditions of release in order to get out of custody following his arrest due to family and health-related reasons. [*Id.* at 28-37]. Finally, Defendants argue that circumstances radically changed since their agreement with the Government because, almost immediately after entering into the agreement concerning release, the Government, through seizure and search warrants I issued, seized approximately $19 million worth of DMAA from Hi-Tech's business, endangering the company's survival and placing at imminent risk the continued

employment of scores of employees. [*Id.* at 38-41]. They also point out that the current charges in the superseding indictment do not involve DMAA. [*See passim* Doc. 7].

After hearing arguments from the parties and reviewing the record in this case and in No. 1:13-cv-3675-WBH, I conclude that the motion to amend should be **DENIED**.[1] The gist of Defendants' argument is that I should re-evaluate Judge Hunt's conclusions in *United States v. Quantities of Finished ands In-Process Goods*, Civil Action File No. 1:13-cv-3675-WBH (N.D. Ga.), *appeal pending* Nos. 17-13376-K & 17-13376-KK (11th Cir.). In that action, the Food and Drug Administration ("FDA") sought seizure and forfeiture of a large quantity of DMAA from Hi-Tech. Hi-Tech and Wheat filed claims to the *res* and opposed the relief sought by the FDA. No. 1:13-cv-3675-WBH , at Doc. 11. On April 3, 2017, Judge Hunt held that (1) DMAA is not a botanical and thus not a dietary ingredient, *see* 1:13-cv-3675-WBH, Doc. 140 at 9; (2) DMAA is a food additive and thus is presumed unsafe unless there is in effect, and it or its intended use are in conformity with, a regulation

[1] I recognize that the Government contended at the hearing that I should evaluate the present motion under the more strict standard of evaluating motions for reconsideration. I reject that argument not due to its legal inaccuracy but because I almost always give Defendants an opportunity to present arguments or evidence in good faith that either my detention decision was wrong or conditions of release were unnecessarily restrictive. More importantly, Defendants' motion fails whether it is viewed as a motion to amend the conditions or for reconsideration.

prescribing the conditions under which the food additive may be safely used under 21 U.S.C. § 348(a)(2), and there is no such regulation, *see id.*; (3) Hi-Tech did not establish that DMAA satisfied the "food additive" exception for foods that are "Generally Recognized as Safe" ("GRAS"), 21 U.S.C. §§ 321(s), 348(b), *see id.* at 9-10; and (4) products for human consumption containing DMAA are adulterated foods under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and subject to seizure under 21 U.S.C. § 334. *See id.* 140 at 12. That same date, the Clerk entered judgment

> as to all claims in favor of the Government and against the Defendants undermined quantities of all articles of finished and in-process foods, raw ingredients (bulk powders, bulk capsules) containing DMAA with any lot number, size, or type container, whether labeled or unlabeled and also against Claimants Hi-Tech Pharmaceuticals, Inc., and Jared Wheat as to the forfeiture action, and to all claims in the suit originally filed in the District Court for the District of Columbia as 1:13-CV-1747, later transferred to this Court as 1:14-CV-2479[2] and later merged into this action.

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[2] In *Hi-Tech Pharmaceuticals, Inc., v. Hamburg*, No. 14-cv-2479-WBH, Hi-Tech sought declaratory and injunctive relief against the FDA and the Department of Health and Human Services, claiming that the defendants' actions with regard to Hi-Tech's DMAA-containing products violated (1) the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994), amending the FDCA, 21 U.S.C. § 301-399, and (2) the Administrative Procedures Act, 5 U.S.C. § 500 *et seq.*

Id., Doc. 141. Judge Hunt subsequently denied Hi-Tech and Wheat's motion for motion for reconsideration/to vacate, *id.*, Doc. 142, and motion to stay, *id.*, Doc. 143. *Id.*, Doc. 148. That action is currently on appeal to the Eleventh Circuit. *Id.*, Doc. 149.

At oral argument before me, Defendants conceded that their evidence and arguments presented to me in their challenge to the evidentiary and legal conclusions underlying Judge Hunt's order in 1:13-cv-3675, were the same evidence and arguments presented to and rejected by Judge Hunt. Thus, it seems to me that Defendants are seeking to have me revisit Judge Hunt's conclusions, hoping for a more favorable result. Even though this is a criminal action and the issue before the Court is what actions Defendants are or are not permitted to do while on pretrial release, whereas the issue in the action before Judge Hunt was whether the quantity of DMAA at issue was subject to forfeiture, collateral estoppel mandates that Defendants' arguments be rejected.

Collateral estoppel forecloses relitigation of an issue of fact or law where an identical issue has been fully litigated and decided in a prior suit. *See Grosz v. City of Miami Beach, Fla.*, 82 F.3d 1005, 1006 (11th Cir. 1996); *see also Ashe v. Swenson*, 397 U.S. 436, 443 (1970) (" 'Collateral estoppel' is an awkward phrase, but it stands for an extremely important principle in our adversary system of justice. It means

simply that when an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in any future lawsuit. Although first developed in civil litigation, collateral estoppel has been an established rule of federal criminal law. . . .") (citation omitted). " 'Collateral estoppel bars relitigation of an issue previously decided if the party against whom the prior decision is asserted had 'a full and fair opportunity' to litigate that issue in an earlier case.' " *United States v. Weiss*, 467 F.3d 1300, 1308 (11th Cir. 2006) (quoting *Blohm v. Comm'r of Internal Revenue*, 994 F.2d 1542, 1553 (11th Cir. 1993), and *Allen v. McCurry*, 449 U.S. 90, 94-95 (1980)); *see also Christo v. Padgett*, 223 F.3d 1324, 1339 (11th Cir. 2000) (citations omitted) (same). It applies where (1) the issue in the pending case is identical to that decided in a prior proceeding; (2) the issue was necessarily decided in the prior proceeding; (3) the party to be estopped was a party or was adequately represented by a party in the prior proceeding; and (4) the precluded issue was actually litigated in the prior proceeding. *Id.* (citing *Blohm*, 994 F.2d at 1553; *In re Raiford*, 695 F.2d 521, 523 (11th Cir. 1983)). Although not an exact fit—because issues resolved in an earlier civil action are not subject to preclusion in a later criminal

action[3]—for purposes of the matter before me (which are not based on proof beyond a reasonable doubt but rather a reasonableness standard, that is, 18 U.S.C. § 3142's mandate that whatever conditions of release are imposed on a defendant be the least restrictive conditions to reasonably assure the safety of the community) collateral estoppel principles provide guidance for how Defendants' motion should be treated.

First, although there are other issues in the matter before me, the overall issue is whether products for human consumption containing DMAA are adulterated foods under the FDCA. Defendants argue that Judge Hunt's conclusions are flawed because

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[3] In *Standefer v. United States*, 447 U.S. 10 (1980), the Supreme Court drew a sharp distinction between civil and criminal cases for purposes of collateral estoppel. Chief Justice Burger, writing for a unanimous Court, noted that criminal cases "involve[ ] an ingredient not present in [civil cases]: the important federal interest in the enforcement of the criminal law." *Id.* at 24. On the civil side, where disputes arise out of private rights, "no significant harm flows from enforcing a rule that affords a litigant only one full and fair opportunity to litigate an issue, and there is no sound reason for burdening the courts with repetitive litigation." *Id.* When a criminal prosecution is mounted, however, policy considerations unique to the criminal justice system often "outweigh the economy concerns that undergird the estoppel doctrine." *Id.* at 25. Indeed,

> [T]he purpose of a criminal court is . . . to vindicate the public interest in the enforcement of the criminal law. . . . The public interest in the accuracy and justice of criminal results is greater than the concern for judicial economy professed in civil cases.

Id. (citation omitted).

they are based on either insufficient or defective evidence, and thus DMAA-containing food products are not adulterated food under the FDCA such that they should be allowed to manufacture, market, and sell products containing DMAA. So, the issues in both proceedings are the same.

Second, the issues that Defendants seek to relitigate in front of me were decided in the prior proceeding. I understand that the prior proceeding did not result in an order banning Defendants' manufacture, marketing, distribution, or sale of DMAA-containing products but rather involved whether the DMAA *res* in that case was subject to seizure as adulterated food, but there was nothing unique about the DMAA in the earlier case that differentiates it from DMAA generally, and Judge Hunt's conclusions did not seek to draw a distinction between the DMAA in his case and DMAA generally. Instead, his findings and conclusions applied to DMAA generally.

Third, Defendants were either parties to the earlier proceeding or their interests were represented. Wheat and Hi-Tech were claimants in the earlier proceeding, and thus actively involved, and Schopp was Director of Contract Manufacturing for Hi-Tech, [Doc. 7 at 2]; *see also* Pretrial Services Report dated 10/04/2017; and thus his interest was more than adequately represented in the earlier case and he had a "full and fair opportunity" to litigate.

Fourth, the issue in this case was actually litigated in the earlier action: whether products for human consumption containing DMAA for human consumption are adulterated foods under the FDCA. Judge Hunt held that they were, leading to the seizure and forfeiture of the DMAA in that case. In this case, the question is whether Defendants should be prohibited from selling DMAA-containing products while on pretrial release.

Defendants are bound by the rulings issued by Judge Hunt that DMAA-containing products for human consumption constitute adulterated food under the FDCA, unless and until said order is reversed by the Eleventh Circuit. The introduction of adulterated food into interstate commerce is a crime. *See* 21 U.S.C. § 331(b) (prohibiting the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce); *id.* § 333(a) (imposing criminal penalties for violation of § 331). One of the conditions of Wheat's and Schopp's pretrial release is the prohibition on committing crimes. [*See* Docs. 22 at 2, 26 at 2]. Hi-Tech similarly cannot commit acts which violate the law, and therefore I am not going to vacate the DMAA-prohibition order as to it, either.

I recognize that prohibiting Defendants from manufacturing, marketing, distributing, and selling DMAA-containing products might cause Hi-Tech to lay off

many of its employees. However, since manufacturing, marketing, distributing, and selling DMAA-containing products by Hi-Tech would be in violation of federal law unless Judge Hunt's order is vacated or reversed, the unfortunate hardship that the employees will suffer is beyond my authority to militate. As for Wheat's claim that he agreed to the condition under duress, even assuming that fact for purposes of this Order, I am unable to allow Wheat to commit a violation of federal law.

That the Government in Judge Hunt's case did not successfully seek or obtain the relief that it obtained from me is irrelevant. Judge Hunt's conclusion—that DMAA-containing foods for human consumption are adulterated foods—is binding on these Defendants unless and until reversed or revised by the Eleventh Circuit. Issue preclusion similarly prevents me from revisiting Judge Hunt's conclusion, and so starting with the fact that DMAA-containing foodstuffs are adulterated foods, it flows that Defendants' manufacture, marketing, distribution, and sale of these materials constitutes a crime in violation of federal law. Since while on pretrial release Defendants may not commit another federal offense, the DMAA ban in the Hi-Tech order and Wheat's and Schopp's conditions of release are appropriate, least restrictive conditions to reasonably assure the safety of the community.

Accordingly, for all of the reasons stated above, Wheat and Hi-Tech's motion,[Doc. 45], as adopted by Schopp, [Doc. 56], to remove the prohibition against their manufacturing, marketing, distributing, and selling DMAA-containing products is **DENIED**.

IT IS SO ORDERED, this the 13th day of December, 2017.

ALAN J. BAVERMAN
UNITED STATES MAGISTRATE JUDGE