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

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., *et al*.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

CLAIMANTS HI-TECH PHARMACEUTICALS, INC. AND JARED WHEAT'S REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO STAY PENDING RECONSIDERATION AND APPEAL

I. INTRODUCTION

Claimants Jared Wheat and Hi-Tech Pharmaceuticals, Inc. (collectively "Hi Tech," or "Claimants") respectfully submit this memorandum of law in reply to the Government's Opposition, Doc. 145, and in further support of their motion to stay pending reconsideration and appeal of the Court's April 3, 2017 grant of summary judgment on all claims in favor of the Government and denial of Claimants' motion for summary judgment. Doc. No. 140 ("April 3 Order"); Doc. 141 ("April 3 Judgment").

Although the Court adopted Claimants' position that DMAA is present in geraniums, and refuted the Government's many weak arguments to the contrary, it surprisingly held that DMAA should not be considered a dietary ingredient under the Dietary Supplement Health and Education Act of 1994 ("DSHEA") because there was purportedly no evidence in the record that DMAA could be extracted from geraniums in "usable quantities" and granted summary judgement in favor of the Government. April 3 Order at 9. Thus, the Court ordered that:

> The Clerk is **DIRECTED** to enter judgment as to all claims in favor of the Government and against the Defendants undetermined 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 as listed in the amended complaint, [Doc. 25 as further amended by Doc.138], and also against Claimants

> Hi-Tech Pharmaceuticals, Inc., and Jared Wheat in the forfeiture action. The Clerk is further **DIRECTED** to enter judgment as to all claims in favor of Defendants and against Plaintiffs in the suit originally filed in the District Court for the District of Columbia, *Hi-Tech Pharmaceuticals, Inc. v. FDA, et al.*, No. 1:13-CV-1747 (D.D.C.), later transferred to this Court as *Hi-Tech Pharmaceuticals, Inc. v. FDA, et al*., 1:14-CV-2479 (N.D. Ga.), and even later merged into this action.

April 3 Judgment.

As demonstrated below, because a stay will preserve the status quo while novel issues of law are considered and appealed, and because the Government consents, the Court should grant Claimants' application for a stay.

I. The Court Should Stay Its April 3 Order Pending Resolution of this Motion for Reconsideration, or, Alternatively, Pending Appeal of that Order

A. The Government Consents to the Stay of the Order

Claimants have satisfied the requirements for a stay pending their motion for reconsideration and, if necessary, appeal of the order and judgment. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Venus Lines Agency v. Cvg Industria Venezolana De Aluminio*, C.A., 210 F.3d 1309, 1313 (11th Cir. 2000); *see also* LR 7.2(E); Fed. R. Civ. P. 62(b); Fed. R. App. P. 8(a). Indeed, the Government consents to a stay of the April 3 Order "directing the destruction of the condemned

and forfeited articles" through the resolution of Claimants' motions for reconsideration and, if necessary, appeal. Doc. 145 at 5.

B. The Government's Attempts to Transform the April 3 Order into an Injunction Against Hi-Tech Should Be Denied

However, the Government cannot bring itself to entirely agree with Claimants. As a result, although the Government consents to a stay of the destruction of the "seized, condemned and forfeited articles" at issue in this litigation, the Government objects to "a stay of the **entire** Order and the blessing of Hi-Tech's continuing sales of DMAA-containing products to the public." Doc. 145 at 2 (emphasis added). Strangely, the Government argues that a stay of the "entire Order" will permit Hi-Tech to "place its financial interests above the public health," such that Hi-Tech should be effectively enjoined from selling and distributing DMAA and DMAA-containing products that are outside the scope of the April 3 Order and Judgment, or any other legal action to date. *Id*. Simply put, the Government's request for such an *in personam* injunction in this *in rem* action that it chose to bring has no legal or statutory support and is wrong. *See* Fed. R. Civ. P. 65 (setting forth the procedure for obtaining an injunction).

C. This Is an *In Rem* Proceeding

Despite the Government's new request to enjoin Hi-Tech from engaging in legitimate business activities, Hi-Tech is not a defendant in an action brought by

the Government, but rather is the Claimant. As set forth in the Amended Complaint for Forfeiture filed by the Government, Doc. 25, this proceeding is an *in rem* forfeiture proceeding, brought pursuant to 21 U.S.C. § 334 (forfeiture statute). Thus, the defendants in this case are the undetermined quantities of all articles of finished and in-process foods set forth first in the caption of the case and later throughout the Government's Amended Complaint seeking forfeiture, not Hi-Tech. *See* Doc. 25.

As the U.S. Department of Justice's website explains: "**Civil judicial forfeiture** is an *in rem* (against the property) action brought in court against the property . . . ." https://www.justice.gov/afp/types-federal-forfeiture (last accessed May 4, 2017) (emphasis in the original).[1] An *in rem* action may, as here, "feature claimants to property, but the claimants are not formally parties to the action." *Taul ex rel. United States v. Nagel Enters*., 2016 LEXIS 7975, *7 (N.D. Ala. Jan. 25, 2016) (noting that "civil forfeiture actions proceed on the theory that the 'thing

[1] Similarly, the U.S. Attorney's Manual explains in the context of civil forfeiture settlements, "[a]ny settlement that purports to 'forfeit' property binds only the parties to it and forfeits only that interest in the property that the claimant possesses." U.S.A.M. 9-113.410 (Civil Judicial Forfeiture Settlement Procedures) https://www.justice.gov /usam/usam-9-113000-forfeiture-settlements#9-113.410 (last accessed May 4, 2017).

is primarily considered the offender.'") (citing *J.W. Goldsmith, Jr.-Grant Co. v. United States*, 254 U.S. 505, 511 (1921)).

As such, the April 3 Order and Judgment in the *in rem* proceeding brought by the Government applies only to the specific, seized goods listed within the four corners of the Government's amended complaint. The April 3 Order does not apply to any of Hi-Tech's products that are not being held in detention by the U.S. Marshal, nor does it apply to Hi-Tech's products already in the stream of commerce.

If the Government wants to enjoin Hi-Tech from selling DMAA products, it has at its disposal a range of different enforcement actions enumerated under the Food, Drug, and Cosmetic Act (the "Act"). As the FDA's own webpage, "Types of FDA Regulatory Actions," notes, among other ways, the FDA can act by issuing or instituting:

> Warning Letters – Warning Letters are sent to the individuals or firms, advising them of specific noted violations. These letters request a written response as to the steps which will be taken to correct the violation. These letters constitute one form of warning that can be issued under current Agency policy.
>
> Seizure – A seizure is an action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the Act. The purpose of such an action is to remove specific goods from the stream of commerce.

> Injunction - An injunction is an order by a court that requires an individual or corporation to do or refrain from doing a specific act. FDA may seek injunctions against individuals and/or corporations to prevent them from violating or causing violations of the Act.

Id.

Despite sending warning letters to other manufacturers that used DMAA, the FDA did not send Hi-Tech a warning letter. MSJ Wenik Decl.,[2] Ex. 19, April 21, 2012 Press Release. And despite recently moving for an injunction against another manufacturer that used DMAA, the Government did not move under Rule 65 for an injunction against Hi-Tech. *United States of America v. Viviceuticals, Inc. et al*., Docket No. 8:15-cv-01893 (C.D. Ca.), Doc. 1.

Instead, here, the FDA purposefully sought the seizure and forfeiture of specific items of Hi-Tech's products. Relying solely on cases involving the FDA's injunctive powers, the FDA now asks the Court to transform its April 3 Order into an injunction, to "deter Hi-Tech and others from introducing adulterated food into interstate commerce." Doc. 145 at 10. *See* 1-10A Moore's Manual--Federal Practice and Procedure § 10A.01 (Matthew Bender 3d ed. 2017) (defining

[2] All citations to the MSJ Wenik Decl. refer to the declaration of Jack Wenik, Esq., submitted in support of Claimants' Motion for Summary Judgment, Doc. 108-3, and the exhibits thereto, Docs. 108-4 to 108-8.

injunction as a "device used by a court to either require or prevent future conduct on the part of the person who is subject to the injunction"); § 10A.02 ("Rule 65 is a procedural device which specifies the methods that a party must use to obtain any type of injunction and was designed to protect against abuse of the injunction remedy"). For example, in furtherance of its argument, the Government relies upon *United States v. Rx Depot, Inc.*, 438 F.3d 1052 (10th Cir. 2006). In that case, Rx Depot admitted to violating the Act and entered into a consent decree of permanent injunction. *Id*. The Government subsequently sought disgorgement of Rx Depot's profits. Similarly, the Government relies upon *United States v. Universal Mgmt. Servs*., 191 F.3d 750 (6th Cir. 1999). Like *RxDepot*, *Universal Mgmt. Servs*. revolved around whether the appellants violated a permanent injunction against distribution of products that the FDA alleged violated the Act.

In contrast to the cases relied upon by the Government, this action is an *in rem* action. The defendants here are the specifically enumerated and seized articles of Hi-Tech's products. If the Government wishes to stop Hi-Tech from selling certain products, it can institute other, properly filed, legal proceedings. The Government should not be permitted to *sua sponte* transform this *in rem* proceeding into an *in personam* one against Hi-Tech.

In the event that the Government chooses to seek an injunction against Hi-Tech in an attempt to curtail Hi-Tech's on-going business activities, the Government will be substantially expanding its potential liability under the Civil Asset Forfeiture Report Act of 2000 ("CAFRA"). If Claimants prevail in such a circumstance, the Government will be liable not only for "reasonable attorney fees and litigations costs reasonably incurred by the claimant," but also for "post judgment interest" as well as "an imputed amount of interest that [the proceeds] would have earned at the rate applicable to the 30-day Treasury Bill. . ." 28 U.S.C. §§2465(b)(1)(A)-(C).

D. Hi-Tech's Press Releases Are Irrelevant to The Legal Issues Before the Court

Finally, citing to press releases issued by Hi-Tech,[3] the Government claims that the Court's April 3 Order needs to be transformed into an injunction because "despite the public harm that ensues from violations of the Act . . . Hi-Tech is

[3] In contrast, the FDA's own website contains numerous inaccuracies regarding DMAA, including falsely claiming that DMAA is an "is an amphetamine derivative," and that the "FDA is not aware of any reliable science indicating that DMAA exists naturally in plants." https://www.fda.gov/food/dietarysupplements/ productsingredients /ucm346576.htm (last accessed May 5, 2017). Moreover, the FDA's website fails to mention that scientists funded by the FDA found DMAA in geraniums.

asking that the Court set aside any legal impact of its Order." Doc. 145 at 11. That is not what is at issue here.

Indeed, the public interests protected by DSHEA will be unaffected if a stay is granted pending reconsideration or appellate review. The relevant interest under DSHEA is to provide consumers access to, and accurate information about, dietary supplements. Pub. L. 103-417, 108 Stat. 4325 (1994); *see also All. for Nat. Health US v. Sebelius*, 775 F. Supp. 2d 114, 129 (D.D.C. 2011). The requested stay would simply act to maintain the *status quo*—the products at issue are already seized and under the control of the U.S. Marshal. The very nature of this *in rem* action—that Hi-Tech's products are seized and in the control of the Government—consequently means that the continued existence of the products has no effect on the public interest pending resolution of Claimants' motion.

Moreover, the overwhelming evidence in the record demonstrates that, contrary to the Government's claims of "public harm," DMAA is safe for human consumption. As set forth in Claimants' Motion for Summary Judgment, Doc. 108-1 at 18, not a single serious illness or death has been shown to have been caused by DMAA. Since 2010, Hi-Tech has sold over 200 million doses of DMAA containing products with only a handful of adverse events of any sort. MSJ Wenik Decl., Ex. 2, Declaration of Michael Lumpkin, Ph.D., DABT ("Lumpkin Decl.") at

¶¶ 98-99; Ex. 65, Deposition Transcript of Jared Wheat at 174:16-22. The safety of DMAA is also reflected in a District Court decision which rejected as unreliable and unfounded the testimony of the plaintiff's experts in the wrongful death case of Michael Sparling that his death was caused by DMAA. MSJ Wenik Decl., Ex. 36, Order, *Sparling v. Doyle, et al.*, Dkt. No. EP-13-CV-323-DCG (W.D. Tex. July 27, 2015).

In contrast to the Government's self-serving and unsupported allegations regarding the need to protect the public from Hi-Tech's products, Claimants have set forth a substantial amount of scientific research pointing to DMAA's safety. In the wake of serviceman Michael Sparling's death, the Department of Defense ("DoD") conducted a comprehensive case control study of DMAA involving hundreds of cases. Among other things, the study, completed in June 2013, found: 1) it was unlikely that DMAA played a significant role in the deaths of four service personnel who had consumed DMAA, 2) there was no statistically significant association between DMAA use and adverse medical events or outcomes, and 3) soldiers consuming DMAA had 40% **lower** odds of having an adverse medical outcome. MSJ Wenik Decl., Ex. 41, Col. John Lammie, Report of the Department of Defense 1,3 Dimethylamylamine (DMAA) Safety Review Panel, June 3, 2013 (the "DoD Study"), stamped GOV-02688 through GOV-02796, at GOV-002714-

15, GOV-002736. Similarly, several peer reviewed studies examined the physiological effects of DMAA and found, at worst, transient increases in blood pressure that did not have clinical significance. MSJ Wenik Decl., Ex. 37, Elkind Decl. at ¶¶ 52-68; Ex. 2, Lumpkin Decl. at ¶¶ 43-54; 68-75.

Perhaps most importantly, there is a dearth of expert testimony in the record to challenge the safety of DMAA.[4] Claimants have presented a comprehensive slate of experts as to DMAA's safety including a toxicologist, Dr. Michael Lumpkin, a pharmacologist/physician, Dr. Matthew Lee, a board certified neurologist, Dr. Mitchell Elkind, and a family medicine physician, Dr. Marvin Heuer. All agree that Hi-Tech's DMAA containing products are safe when used as recommended.

Finally, during the four years of litigation in this matter, during which DMAA-containing products have continued to have been sold, there has not been a single incident or adverse event report that would justify the Government's over-the-top and unsupported concerns regarding DMAA. If there was one, it is undoubtedly sure that the Government would have trumpeted it to the Court. Thus,

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[4] In contrast, the record as set forth at length by Claimants makes clear that the FDA, prompted by Amy Eichner, had an agenda to unilaterally ban DMAA from the marketplace, and provided millions of dollars in funding to mold the science in a classic case of the ends purportedly justifying the means.

by any stretch of the imagination, "little if any harm" will befall the public as a result of this stay pending appellate review. *Ruiz*, 650 F.2d at 565.

Conclusion

For each of the foregoing reasons, Claimants respectfully request that the Court grant their motion for stay pending resolution of its motion for reconsideration and/or appeal.

Respectfully submitted,

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this 8th day of May, 2017.

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