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

LABMD, INC., PLAINTIFF, v. FEDERAL TRADE COMMISSION, DEFENDANT.	)	CIVIL ACTION NO.: 1:14-CV-810-WSD

PLAINTIFF'S RESPONSE TO DEFENDANT FTC'S CONSOLIDATED BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The core issues in this case are (1) whether Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, empowers Defendant Federal Trade Commission ("FTC" or "Commission") to create a "common law" of protected health information ("PHI") data security, using consent orders and internet posts, that over-files and contradicts federal PHI regulations, and if so, (2) whether Section 5's general prohibition of unfair trade practices provides constitutionally sufficient prior warning to doctors, hospitals and medical laboratories of what FTC requires, given that PHI regulatory compliance is apparently not enough. Here, the controlling authorities and compelling equities stand for denial of FTC's motion and for issuance of a preliminary injunction against FTC's enforcement action styled *In the matter of LabMD*, Dkt. No. 9357.

First, FTC issued a final order (the "LabMD Order") on January 16, 2014, taking for itself the power to add its own arbitrary and idiosyncratic requirements to the Department of Health and Human Services's ("HHS") HIPAA regulations for PHI data security[1] Because the LabMD Order is the Commission's final word

[1] HIPAA refers to the Health Insurance Portability and Accountability Act of 1996, as amended. HIPAA delegates to HHS, and not FTC, authority to "adopt security standards" for "health information" created or received by "health care providers" 42 U.S.C. § 1320d-(2)(d)(1) and 42 U.S.C. § 1320d(3) and (4) (defining the terms "health information" and "health care provider"). HHS has

on its jurisdiction, but is not a cease and desist order, the decision is reviewable here.

Second, even if the LabMD Order was only a non-final or interim step in the administrative process for issuing cease and desist orders, numerous cases confirm that district courts have subject-matter jurisdiction. There is no Supreme Court case, or any other authority, supporting FTC's blanket claim that Article III courts are always prohibited from "interfering" with ongoing administrative proceedings. *See* FTC Br. at 12.

In fact, application of FTC's own four-factor test, *see* FTC Br. at 24, demonstrates that judicial review is proper now. Specifically:

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exercised this rulemaking authority. 65 Fed. Reg. 82,462 (Dec. 28, 2000) (HIPAA privacy rule); 68 Fed. Reg. 8,334 (Feb. 20, 2003) (HIPAA security rule); 78 Fed. Reg. 5566 (Jan. 25, 2013) (Omnibus Final Rule). Congress reaffirmed HHS's jurisdiction over the information security of HIPAA-covered entities, and excluded FTC jurisdiction in that area, in giving HHS the exclusive responsibility for promulgating rules regulating security breaches of HIPAA-covered entities, and giving the FTC only such responsibility in connection with entities not covered by HIPAA, in Sections 13402 and 13407 of the Health Information Technology For Economic And Clinical Health (HITECH) Act, Title XIII of Division A And Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009), codified at 42 U.S.C. §§300jj *et seq.*; §§17901 *et seq*.

(A) Are the FTC's jurisdictional order and the ongoing enforcement action affecting the legal rights and obligations of LabMD?

Yes. The LabMD Order claims FTC may add, by "common law," new PHI data security obligations on top of HHS's regulations and that LabMD must comply with them.

(B) Are the FTC's jurisdictional order and the ongoing enforcement action impairing LabMD's daily operations?

Yes. Although LabMD continues to provide physicians with access to patient records, FTC has driven the company into the ground. LabMD has been forced to lay off all but one employee and has stopped offering cancer-detection services to its physician clients. LabMD cannot resume offering cancer-detection services while FTC continues its assault.

(C) Do the merits of this dispute turn primarily on purely legal questions?

Yes. The facts are generally undisputed, and this dispute turns on two legal questions: (1) Whether Section 5 authorizes FTC to create new PHI data security requirements on top of HHS's regulations through an administrative "common law" of consent orders and internet posts; and (2) if so, whether FTC gave LabMD and all other doctors, hospitals and medical laboratories the requisite constitutional and statutory fair notice of prohibited and permitted conduct.

(D) Is pre-enforcement review efficient?

Yes. FTC lacks legal authority to over-regulate here. Therefore, FTC should be enjoined **before** it destroys LabMD. FTC enforcement action that exceeds the Commission's authority is contrary to the public interest.

Fourth, LabMD is suffering immediate irreparable harm. FTC's enforcement action, which began in January, 2010, has cast a shadow over its operations. Moreover, because FTC did not tell LabMD what, specifically, it did "wrong" until it provided LabMD with an "expert" report on March 18, 2014, which generally avers "flaws" occurring at unspecified times between an undefined point in time from 2005 through January, 2010, FTC prevented LabMD from curing such "flaws," thereby providing appropriate assurances to its physician clients and preserving its business.

Fifth, FTC makes deference and finality claims that do not apply here. None of these arguments prohibits the Court from protecting LabMD's constitutional rights or allows FTC to force a company out of business without alleging regulatory violations, much less first specifying the minimum conduct needed to attain compliance.

In this Response, LabMD briefly responds to FTC's Statement of Facts. Then, it addresses FTC's jurisdictional arguments. Finally, it replies to FTC's arguments opposing the issuance of a preliminary injunction.

REPLY TO STATEMENT OF FACTS

There are two significant undisputed facts in this case. First, FTC admits the LabMD Order is final agency action. FTC says: "The Commission's ruling represents *a definitive interpretation of the application of Section 5* [15 U.S.C. § 45] *to data security* . . . ." FTC Br. at 24. This admission means LabMD is entitled to judicial review.

Second, LabMD has submitted two declarations from CEO Michael J. Daugherty which describe FTC's irreparable harm to LabMD's business.[2] FTC does not (indeed, cannot), dispute these declarations. This means a preliminary injunction would be proper.

[2] Daugherty Supp. Dec. ¶¶ 4-13.

ARGUMENT AND CITATION TO AUTHORITY

I. FTC's Motion to Dismiss Fails Because This Court Has Subject-Matter Jurisdiction.

FTC argues that this case must be dismissed for lack of subject-matter jurisdiction.[3] Contrary to FTC's arguments, four distinct, but interrelated, grounds confirm that this Court has subject-matter jurisdiction to address the issues raised by LabMD's motion for preliminary injunctive relief. Whether these grounds are analyzed independently or in combination, the outcome is the same: This Court has subject-matter jurisdiction.

A. The Commission Has Issued a Final Determination Regarding the Scope of Its Jurisdiction to Regulate HIPAA-Regulated Entities.

On January 16, 2014, the Commission issued the LabMD Order, which declares:

> Contrary to LabMD's contention, Congress has never enacted any legislation that, expressly or by implication, forecloses the Commission from challenging data security measures that it has reason to believe are 'unfair . . . acts or practices;[4] and
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> ***
>
> LabMD has not identified a single provision in any of these statutes that expressly withdraws any authority from the Commission.[5]

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3 FTC. Br. at 11.

4 Verified Compl., Ex. 2 at 10.

5 Verified Compl., ¶ 69, and Ex. 2.

Further, FTC now admits that the LabMD Order "a determinative interpretation of the application of Section 5."[6] Thus, the Order is "final agency" action by the FTC Commission with respect to its "definitive interpretation of Section 5 [15 U.S.C. § 45] to data security and the Commission's authority to impose requirements on HIPAA-regulated medical service providers, and those requirements may be in addition to and beyond what HHS has imposed under HIPAA. Specifically, the Commission concludes:

> In sum, we reject LabMD's contention that the Commission lacks authority to apply the FTC Act's prohibition of "unfair … acts or practices" to data security practices, in the field of patient information or in other contexts; and we decline to dismiss the Complaint on that basis.[7]

No further action with respect to that legal issue is required. Further, FTC deems the LabMD Order to be "final" at least with respect to the Commission's position as to the scope of its authority "in the field of data security generally and "patient information" specifically by submitting the Order to the Eleventh Circuit and the District Court of New Jersey as supplemental legal authority.[8] Then, the

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6 FTC Br. at 24.

7 Verified Compl., Ex. 2 at 14.

8 Verified Compl., ¶¶ 70-71, and Ex. 3 (*"*Notice of Supplemental Authority" submitting the LabMD Order to Judge Salas in the matter styled as *FTC v. Wyndham Worldwide Corp. et al.*, No. 2:13-cv-01887-ES-JAD).

FTC asked those courts to apply *Chevron*[9] deference to the Order.[10] Only final agency actions construing a statute are entitled to *Chevron* deference.[11]

Because FTC has treated the LabMD Order as final agency action, the scope of FTC's authority is now reviewable. *Sackett v. EPA*, 132 S. Ct. 1367 (2012). The Eleventh Circuit already has concluded that it does not have jurisdiction over this lawsuit unless and until a cease and desist order is issued because only such FTC orders are reviewable in the courts of appeals.[12] All other final agency actions by FTC are reviewable in the federal district courts under 28 U.S.C. § 1331 and 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.").[13] Section 702 applies to the non-APA claims. Thus, even if the LabMD Order is not final agency action, the legal wrong suffered by LabMD is now reviewable.

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9 *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

10 FTC Br. at 23-24, 28; Verified Compl., ¶¶ 70-71 & Ex. 3 at 6.

11 *Franklin Fed'l Sav. Bank v. Dir. Office of Thrift Supervision*, 927 F.2d 1332, 1337 (6th Cir. 1991) ("When an agency has acted so definitively that its actions are defended based on Chevron, we believe that its action should be treated as final."); *Air Brake Sys. v. Mineta*, 357 F.3d 632, 641-644 (6th Cir. 2004); *see also United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

12 Verified Compl., Ex. 1.

13 *Id.*

FTC glosses over the LabMD Order by citing *FTC v. Standard Oil*, 449 U.S. 232 (1980), for the proposition that FTC's administrative complaint is not by itself final agency action under the Administrative Procedure Act.[14] But *Standard Oil* and its progeny do not apply here because LabMD is not challenging the issuance of an administrative complaint against it. Rather, LabMD is challenging the final agency action, reflected in the LabMD Order, in which FTC claims broad authority over PHI data security in a manner that devours the explicit regulatory authority Congress delegated to HHS.[15] The LabMD Order is final action. LabMD has been adversely affected and is aggrieved. All of LabMD's claims are reviewable under 5 U.S.C. §§ 702 or 704.

FTC's other cases are not controlling. The LabMD Order is not the type of preliminary decision addressed in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), nor does judicial review here upset the detailed administrative processes at issue in *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994).

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[14] FTC Br. at 20-23.

[15] Likewise, FTC's cases such as *Frito-Lay, Inc. v. FTC*, 380 F.2d 8 (5th Cir. 1967), that held a petitioner could not challenge FTC's conduct in an administrative proceeding until a final order had issued do not apply. Those decisions never addressed the issuance of a Commission order that was then touted as supplemental legal authority as to the scope of the Commission' authority and did not address agency action that is causing LabMD to go out of business.

In *Ewing*, the Supreme Court noted that Congress enacted a careful scheme of what decisions were reviewable and when under the underlying statute. *Ewing*, 339 U.S. 600-01. Here, however, Congress has not explicitly foreclosed judicial review of FTC over-regulation or of final FTC jurisdictional orders. More importantly, the concerns identified by Justice Frankfurter in his dissenting opinion are squarely presented here and warrant immediate judicial review:

> Assuming as I do that the Act on its face is not constitutionally defective, the question remains whether it has been so misused by refusal of administrative hearing, together with irreparable injury in anticipation of judicial hearing, as to deny appellee due process of law or to amount to an abuse of process of the courts.

339 U.S. at 875-76 (Frankfurter, J. dissenting).

Thunder Basin solely addressed limitations on jurisdiction to review purely statutory claims before the agency initiated an enforcement action. *Thunder Basin*, 510 U.S. at 205, 216. The only constitutional issue was the timing of the suit. The Court reached the merits of that claim. *Id.* at 219 (Scalia, J., concurring). Here, LabMD is challenging an ongoing enforcement action on constitutional and jurisdictional grounds. Also, unlike 15 U.S.C. § 45, the statute in *Thunder Basin* expressly provided that, absent extraordinary circumstances, "no objection that has not been urged before the Commission shall be considered" by

the court of appeals. 30 U.S.C. § 816(a)(1); *see Thunder Basin*, 510 U.S. at 208-09. *Thunder Basin* does not bar judicial review here.

FTC also argues that the ripeness doctrine precludes judicial review at this time relying on *State of Texas v. United States*, 523 U.S. 296 (1998). FTC Br. at 17-18. But for the same reasons that the LabMD Order is final agency action, the ripeness doctrine does not preclude judicial review. FTC has issued a determinative statement as to its authority, LabMD disputes FTC's scope of authority and LabMD has suffered and is suffering injury. The matter is ripe for adjudication.

In sum, FTC argues Section 5 grants the Commission discretion to adopt "common law" data security standards on top of HHS regulations.[16] FTC has opted to use the LabMD Order as its vehicle for announcing this new authority. Therefore, the LabMD Order is judicially reviewable. *Sackett*, 132 S. Ct. at 1373; *Franklin*, 927 F.2d at 1337.

B. District Courts Have Jurisdiction to Redress FTC Abuses.

Even if the LabMD Order was not final agency action, the Court would still have jurisdiction to redress FTC abuses and irreparable harm prior to issuance of a cease and desist order. *See FTC v. Feldman*, 532 F.2d 1092 (7th Cir. 1976)

[16] FTC Br. at 33 ("Thus, an agency's discretion is 'at its peak' when it decides 'whether to address an issue by rulemaking or adjudication.'").

("*Feldman*"); *E.I. du Pont de Nemours & Co. v. FTC*, 488 F. Supp. 747 (D. Del. 1980) ("*DuPont*"); *Boise Cascade Co. v. FTC*, 498 F. Supp. 772 (D. Del. 1980) ("*Boise Cascade*").[17]

In *DuPont*, the FTC complaint asserted a novel theory concerning practices in a concentrated industry and banned certain public statements on pricing. DuPont did not exhaust its administrative remedies, but instead filed a declaratory judgment action. While upholding FTC's exhaustion defense, the district court also concluded it had subject-matter jurisdiction, explaining "[T]he [FTC] Act does not deprive [district courts] of jurisdiction to review orders issues or actions taken during the course of an FTC administrative proceeding when a "cease and desist" order has not yet issued." *DuPont*, 488 F. Supp. at 751.[18]

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[17] *See also Standard Oil. v. FTC*, 475 F. Supp. 1261, 1282 (N.D. Ind. 1979); *de Nemours & Co.*; *Exxon v. FTC*, 411 F. Supp. 1362, 1369-70 (D. Del. 1976); *Beltone Elec. v. FTC*, 402 F. Supp. 590, 602 (N.D. Ill. 1975); *Times Mirror v. FTC*, No. 78-3422-LEW, 1979 WL 1651 (C.D. Cal. June 13, 1979); *Horizon Co. v. FTC*, No. 76-2031, 1976 WL 1343, at * 14 & n.19 (D.D.C. Nov. 18, 1976); *Sperry & Hutchinson Co. v. FTC*, 256 F. Supp. 136, 144 (S.D. N.Y. 1966); *see also GMC v. FTC*, No. C77-706, 1977 WL 1552, at * 12-14 (N.D. Ohio Nov. 4, 1977); *Pepsico v. FTC*, 343 F. Supp. 396, 399 (S.D. N.Y. 1972); *Coca-Cola v. FTC*, 342 F. Supp. 670, 676-77 (N.D. Ga. 1972).

[18] Although the *Feldman* and *DuPont* courts denied relief to the plaintiffs based on exhaustion and other arguments, the *Feldman* court recognized some circumstances could arise where relief was warranted. The court observed that it would grant relief if "compliance with the subpoena's terms becomes patently vexatious and serious hindrance to the pursuit of respondent's business…" *Feldman*, 532 F.2d at 1098. FTC's enforcement proceedings so far have caused

District court jurisdiction to curb FTC abuses occurring before issuance of a "cease and desist" order makes sense. A court is likely to have to hear evidence (whether through live testimony or submission of affidavits and verified pleadings) to determine whether abuses have occurred and to fashion an appropriate remedy. In contrast, a "cease and desist" order is based on a full administrative record, and fact-finding by the appellate courts is not needed.[19]

This is consistent with what has occurred here. The Eleventh Circuit dismissed a prior petition filed by LabMD in that court because its statutory jurisdiction is limited only to reviewing "cease and desist" orders. Because no "cease and desist" order had been issued, the Eleventh Circuit held that LabMD's claims belonged in the federal district court under 28 U.S.C. § 1331.[20] The current dispute is in the same jurisdictional posture. Thus, this Court has subject-

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LabMD to stop offering cancer-detection services. As these proceedings drag on, LabMD may shutdown entirely before FTC decides whether to issue a "cease and desist" order. And, LabMD has diligently pursued redress before the Commission, the Eleventh Circuit, the district court in the District of Columbia, and then before this Court. At a minimum, the combination of looming irreparable harm to, and diligent pursuit of relief by, LabMD distinguishes this case from *Feldman* and *DuPont*.

[19] In other contexts, appeals courts review specific final agency actions that are based on a full administrative record. *See, e.g.*, 33 U.S.C. § 1369; 42 U.S.C. § 9613; 42 U.S.C. § 7607.

[20] Verified Compl., Ex. 1.

matter jurisdiction, and hearing the dispute does not encroach on the exclusive jurisdiction of the Eleventh Circuit.[21]

C. FTC's Test Supports Jurisdiction.

As an alternative to *Standard Oil*, which does not apply here, FTC proposes application of four of the five factors discussed in *TVA v. Whitman*, 336 F.3d 1236, 1248 (11th Cir. 2003), to determine whether the Court should exercise subject-matter jurisdiction.[22] This test, however, supports jurisdiction.

FTC's first factor asks whether the enforcement action and order at issue affect the legal rights and obligations of the parties.[23] Both the ongoing enforcement action and the LabMD Order do so. The LabMD Order establishes that the Commission may impose data security obligations on HIPAA-regulated medical service providers above and beyond what HHS has imposed under

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[21] Any issues regarding the application of *George Kabeller, Inc. v. Busey*, 999 F.2d 1417, 1420 (11th Cir. 1993), to this dispute have been resolved by the Eleventh Circuit in favor of this Court exercising jurisdiction the LabMD Order and any other related orders.

[22] FTC Br. at 24. *TVA* has five factors, but FTC chooses to mention only four. It explicitly concedes the first factor when it admits that "the Commission's ruling represents a definitive interpretation of the application of Section 5 to data security," and then does not mention it again.

[23] FTC Br. at 24; *TVA*, 336 F.3d at 1248.

HIPAA.[24] Having to look to and comply with FTC directives on data security does impose a new obligation on LabMD.[25]

FTC's second factor is whether the action and LabMD Order have an immediate impact on LabMD's daily operations.[26] As the Daugherty Declarations demonstrate, they clearly have done so. LabMD has laid off 30 employees and has stopped offering cancer-detection services to physicians.[27] There is no greater harm to a business than having to curtail activities and shut its doors.[28] FTC has crippled LabMD because its physician clients do not know, and due to the fact that FTC did not specify what LabMD did "wrong" until after more than four years of investigation and administrative enforcement litigation LabMD cannot prove, whether LabMD has a legally sufficient data security program.

FTC's third factor focuses on whether the dispute involves pure questions of law.[29] The pertinent facts in this case are largely undisputed. The core issues

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24 Verified Compl., Ex. 2 at 14.

25 Baker Decl. ¶¶ 11-12.

26 FTC Br. at 24; *TVA*, 336 F.3d at 1248.

27 Supplemental Daugherty Dec., ¶¶ 4-6.

28 *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d 969, 975 (2nd Cir. 1989)) ("A monetary loss will not suffice [as irreparable injury] unless the movant provides evidence of damage that cannot be rectified by financial compensation. Bankruptcy is such a case.").

29 FTC Br. at 24; *TVA*, 336 F.3d at 1248.

here are legal questions concerning whether FTC may lawfully over-regulate HIPAA regulations and, if so, whether FTC has provided fair notice.

FTC's fourth factor asks whether pre-enforcement review will be efficient.[30] In this case, efficiency demands judicial review, for if the Commission lacks jurisdiction to over-regulate, as LabMD claims, then the grinding administrative litigation must end. There is no efficiency gained by doctors, hospitals and medical laboratories or the general public when FTC abuses its power.

D. FTC's Ultra Vires Agency Action Is Reviewable Now.

Federal district courts have subject matter jurisdiction to redress agency actions that are demonstrably *ultra vires* or unconstitutional, even where a statute requires some agency decisions to be reviewed directly in the court of appeals. *See Sackett*, 132 S. Ct. at 1372-74; *Coca-Cola Co. v. FTC*, 475 F.2d 299, 303 (5th Cir. 1973) ("The most widely recognized exception to the general rule against judicial consideration of interlocutory agency rulings is where an agency has exercised authority in excess of its jurisdiction…"); *XYZ Law Firm v. FTC*, 525 F. Supp. 1235, 1237 (N.D. Ga. 1981) (exhaustion not required "where an agency has clearly exceeded its authority" or the plaintiff asserts a "non-frivolous

[30] FTC Br. at 24; *TVA*, 336 F.3d at 1248.

constitutional right"). Where, as here, an agency has committed a "gross or egregious" jurisdictional error, the Court may grant interlocutory relief. *Am. Gen. Ins. Co. v. FTC*, 496 F.2d 197, 200 (5th Cir. 1974).[31]

Even if APA review is foreclosed, which it is not here, a district court has jurisdiction to redress non-statutory *ultra vires* and constitutional claims.[32] *See Nat'l Parks Cons. Ass'n v. Norton*, 324 F.3d 1229, 1240-41 (11th Cir. 2003) ("final agency action" requirement "inapplicable" to constitutional claims); *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1327-1329 (D.C. Cir. 1996) (ultra vires claims).

FTC makes the remarkable claim that Article III courts never have jurisdiction over ongoing administrative proceedings. FTC Br. at 12, 17. But

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[31] The rule is:

> [A]cts of all officers must be justified by some law, and in case an official violates the law to the injury of an individual the courts generally have jurisdiction to grant relief…. *Otherwise the individual is left to the absolutely uncontrolled and arbitrary action of a public and administrative officer, whose action is unauthorized by any law, and is in violation of the rights of the individual.*

Am. Sch. of Magnetic Healing v. McAnnulty, 187 U.S. 94, 108, 110 (1902) (emphasis added).

[32] 5 U.S.C. § 702 waives sovereign immunity for any "agency actions," even non-final actions, where a declaratory judgment or injunctive relief is requested. *See Trudeau v. FTC*, 456 F.3d 178, 187 (D.C. Cir. 2006). This includes issuance of an FTC administrative complaint. *Standard Oil Co.*, 449 U.S. at 238 n.7.

without exception the authorities cited by FTC to support the proposition that this Court may not protect LabMD and must dismiss the complaint either illustrate why judicial review is appropriate here or do not apply.

For example, *N.C. Bd. Dental Examiners v. FTC*, 768 F. Supp. 2d 818, 823 (E.D. N.C. 2011), recognized that a court has jurisdiction over claims that an agency exceeded its statutory authority and where the plaintiff had no other meaningful opportunity for judicial review exists. The court noted that judicial review is available when a plaintiff presents a substantial showing that its constitutional rights are being violated. That showing was not made there. *See id.* at 824. But LabMD has done so here.[33]

FTC also asserts that it may use consent orders to establish a "common law" of data security standards. This violates 15 U.S.C. § 45(m)(1)(B), which prohibits FTC from "creating" a data-security "common law" through consent orders against non-parties. *See Good v. Altria Grp., Inc.*, 501 F.3d 29, 53 (1st Cir.

[33] *Direct Mktg. Concepts v. FTC*, 581 F. Supp. 2d 115, 116 (D. Mass. 2008) pertained to another federal court action and not any administrative proceedings and did not raise irreparable harm concerns. *POM Wonderful LLC v. FTC*, 894 F. Supp. 2d 40, 43 (D.D.C. 2012) is inapposite because plaintiff filed suit before the agency initiated an enforcement action, irreparable harm concerns were not raised and the full Commission did not issue a final order rejecting that plaintiff's constitutional claims. Likewise, *S.C. Bd. of Dentistry v. FTC*, 455 F.3d 436, 440 (4th Cir. 2006), did not involve constitutional or jurisdictional claims or irreparable harm concerns.

2007) (the FTC Act specifically provides FTC cannot enforce consent orders "against non-parties").

5 U.S.C. § 552(a)(1) requires FTC to publish standards and requirements in the Federal Register and not merely post its data security regime on the Internet. It has not done so. 15 U.S.C. § 45(n) also bars FTC from using the FTC's unilateral, unstated "public policy considerations . . . as a primary basis for" exercising its Section 45 "unfairness" authority. Further, APA Section 552(a)(1) states that agency rules and standards must be published in the Federal Register.

FTC tries to deflect its failure to publish data security rules and standards in the Federal Register through selective quotation of 5 U.S.C. § 552(a)(1), which is then deemed not applicable because "FTC has not adopted any rule subject to that provision . . . ." FTC Br. at 31. However, 5 U.S.C. § 552(a)(1) also applies to substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency. 5 U.S.C. § 552(a)(1)(D) (emphasis added). Enforcement of standards purportedly set through its Guides for Business, Consumer Alerts, staff reports, congressional testimony, and other materials never published in the Federal Register violates this requirement. *Util. Solid Waste*

Activities Grp. v. EPA, 236 F.3d 749, 754 (D.C. Cir. 2001) (internet notice is not an acceptable substitute for publication in the Federal Register).

Because of FTC's multiple statutory violations, LabMD's claims are now reviewable. *See Leedom v. Kyne*, 358 U.S. 184, 188 (1958); *Am. Gen. Ins. Co*. 496 F.2d at 199-200.

Finally, this Court has jurisdiction over LabMD's First Amendment retaliation claim, and that claim also provides additional and independent grounds for an injunction.[34] *Trudeau v. FTC*, 456 F.3d 178, 190-91 (D.C. 2006); *White v. Baker*, 696 F. Supp. 2d 1289, 1312-13 (N.D. Ga. 2010) (First Amendment violations are irreparable harm).

The claim is straightforward. Mr. Daugherty, LabMD's CEO, published a book criticizing the FTC. That is protected speech. Then, the administrative complaint was filed. Official reprisal for constitutionally protected speech violates the First Amendment. *See id.* LabMD has pled all of the elements of a First Amendment retaliation claim. *Compare* Compl., ¶¶ 99-101, 144-50, *with Trudeau*, 456 F.3d at 190-91 nn.22-23; *Smith v. Mosley*, 532 F.3d 1270, 1276 (11th Cir. 2008) (setting forth retaliation elements under this Circuit's law).

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[34] LabMD's 40-page Verified Complaint meets pleading obligations under the satisfies the *Iqbal/Twombly* pleading standard. *See* Verified Compl., ¶¶ 4-5, 7-11, 29-49, 53, 145-50.

FTC urges an "unusually suggestive" test to infer retaliation. FTC Br. at 42. While LabMD does not believe such a restrictive test applies, the pleadings meet that test. FTC enforcement staff informed LabMD of their intent to pursue an enforcement action three days after Mr. Daugherty publicly stated his intent to "blow the whistle" on their actions. (Likewise, they noticed twenty depositions and subpoenaed copies of Mr. Daugherty's book drafts s shortly after publication of Mr. Daugherty's book.) The timing is quite "close." *Cf.* FTC Br. at 42. Moreover, it was only after LabMD brought the FTC's actions to the attention of a federal court that the FTC's staff stopped making written public statements explicitly linking their actions to Mr. Daugherty's book.

II. LABMD IS ENTITLED TO A PRELIMINARY INJUNCTION.

A. LabMD Has Suffered Irreparable Harm By Having to Curtail Its Business Activities.

FTC argues that the "'type of hardship LabMD will experience by awaiting the FTC's decision – 'litigation expense, even substantial and unrecoupable cost' – 'does not constitute irreparable injury.'"[35] That argument is a straw man. LabMD asserts irreparable harm based on injury to the business, loss of customers, and loss of good will that has incurred and continues to be incurred.[36]

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[35] FTC Br. at 45 (quoting *Standard Oil* at 244) (quotation omitted).

[36] Supp. Daugherty Decl. ¶¶ 4-13.

LabMD is literally fighting for its survival as a viable ongoing concern due to FTC's decision to over-regulate the HIPAA regulations.

Due to FTC's actions, LabMD has lost its customers. Its medical malpractice insurer and its D&O insurer already have terminated coverage,[37] and LabMD's CGL insurer has told the company that its policy will not be renewed as of May 2014 due to FTC.[38] Among other things, LabMD needs a CGL policy to rent commercial space and resume laboratory testing.[39] This restriction effectively limits LabMD's operations to providing historical information to its physician clients and prevents the company from rebuilding its operations.[40] LabMD is now merely a shell of its former self, with one employee attempting to carry on for a company that once employed 30 people.[41] And, that shell will collapse without intervention from the Court.

The Eleventh Circuit has recognized that the type of harm affecting LabMD is irreparable. *Odebrecht Constr., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1273-74 (11th Cir. 2013). In that case, a party had no monetary recourse

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37 Daugherty Decl., ¶ 9b; Supp. Daugherty Decl. ¶ 11.

38 *Id.* ¶ 11. LabMD's chief executive officer has asked the GCL insurer to extend the effective date of nonrenewal from May 5, 2014 to May 15, 2014, in light of the Court's hearing on LabMD's motion, which is scheduled for May 7, 2014.

39 *Id.* ¶¶ 10-11.

40 *Id.* ¶ 5.

41 *Id.* ¶ 4.

against a state agency for damages caused by the agency's conduct. *Id.* at 2189 (holding that the party "ha[d] no monetary recourse against a state agency like FDOT because of the Eleventh Amendment"). Like the plaintiff in *Odebrecht*, LabMD cannot recover monetary damages for the harm caused by the FTC and that the FTC continues to cause because of sovereign immunity.[42] "In the context of preliminary injunctions, numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable." *Odebrecht*, 715 F.3d at 1289. Thus, LabMD's inability to recover monetary damages as a matter of law is irreparable harm.

The key point is that the harm being suffered by LabMD threatens the company's existence.[43] *See, e.g.*, *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d 969, 975 (2d Cir. 1989) ("A monetary loss will not suffice [as irreparable harm] unless the movant provides evidence of damage that cannot be rectified by financial compensation. Bankruptcy is such a case.") "Losing a substantial percentage of a store's business, especially when coupled with the closing of the store, is enough to constitute irreparable harm." *Sheikh's, Inc. v. United States*, No. 10-62004-CIV, 2010 WL 5253531 at * 2 (S.D. Fla. Dec. 15,

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[42] *Gary v. F.T.C.*, 526 F. App'x 146, 149 (3d Cir. 2013) *cert. denied*, 134 S. Ct. 476 (2013).

[43] *See also Ruderman ex rel. Schwartz v. Wash. Nat'l Ins. Co.*, No. 08-23401-CIV, 2012 WL 1470236 (S.D. Fla. Apr. 27, 2012) (citing Ford).

2010) ("Plaintiff will suffer irreparable harm without a stay of the administrative action"). Further, LabMD's injury is occurring right now; therefore, its injury is "actual and imminent, not remote or speculative." *Odebrecht*, 715 F.3d 1268 at 1288 (citation omitted).

B. LabMD Is Likely to Prevail on the Merits.

1. FTC's Statement of "Unfairness" Authority Is Boundless and Would Swallow All Existing Regulatory Regimes.

The core question here is the breadth of FTC's Section 5 "unfairness" authority. FTC claims total power unless expressly cabined by Congress, FTC Br. at 26, turning on its head the rule that "an agency literally has no power to act . . . unless and until Congress confers upon it the power to do so." *La. Pub. Serv. Com. v. FCC*, 476 U.S. 355, 374 (1986).

The FTC claims its *ultra vires* "expansion" of jurisdiction is "entitled to *Chevron* deference," citing *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868-69 (2013). But as the Supreme Court has directed in words that are right on point here, the "fox-in-the-henhouse syndrome" of an agency determining its own jurisdiction is to be avoided "by taking seriously, and applying rigorously, in all cases, statutory limits on agencies' authority." *Loving v. IRS*, 742 F.3d 1013, 1022 (D.C. Cir. 2014).

If FTC may lawfully over-regulate HIPAA regulations and attack LabMD using its Section 5 unfairness authority,[44] then it may also lawfully over-regulate drinking water and fine water purveyors, who are meeting all applicable Safe Drinking Water Act requirements, and impose even more stringent drinking water standards. It may over-regulate food products subject to "standards of identity" established by the Food and Drug Administration such as Swiss cheese or spring water. It may over-regulate hazardous waste management practices subject to the Resource Conservation and Recovery Act and long-standing Environmental Protection Agency regulations. And, it may over-regulate in the fields of employment law or nuclear energy or any other of a myriad hundreds of fields. By its telling, there is no end to FTC's power and Section 5, most recently amended by Congress in 1994 to limit the Commission's power, is but a gateway to total regulatory authority.

Congress never intended FTC to have such sweeping and over-riding authority to intervene and impose new and additional requirements on entities

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[44] Oddly, FTC's Unfairness Policy Statement limits unfairness actions to those where the Commission seeks "to halt some form of seller behavior that unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decision-making." FTC's complaint against LabMD is bare of any such allegations. *See* FTC Unfairness Policy Statement (Dec. 17, 1980) *available at* http://www.FTC.gov/FTC-policy-statement-on-unfairness (accessed April 10, 2014).

regulated by expert sister agencies. This is the core issue here. An injunction is required to stop FTC from swallowing the HIPAA data security program and from swallowing any and every regulatory regime that is not to the FTC's liking.[45]

2. *Credit Suisse* Controls.

In *Credit Suisse Securities (USA) LLC v. Billings*, 551 U.S. 265 (2007), the United States Supreme Court set forth the factors to consider to determine when a specific regulatory regime displaces, or implicitly precludes enforcement under, a more general and earlier enacted regulatory scheme. The Court held that the securities laws were "clearly incompatible" with the antitrust laws and therefore, held that the antitrust claims were precluded by the securities law regulatory regime. While *Credit Suisse* specifically addressed the interplay of securities regulation and antitrust law, the test and its underlying logic apply here.[46]

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[45] FTC over-reach has been a major concern because the Commission recognizes no prudential restraints on its authority. *See, e.g.*, Michael Pertschuk, Remarks before the Annual Meeting of the Section on Antitrust and Economic Regulation of the Association of American Law Schools, Atlanta, Georgia (December 27, 1977) (claiming the Commission could use unfairness to regulate the employment of illegal aliens and to punish tax cheats and polluters). Courts have repeatedly cited the Commission's failure to articulate limiting principles for its authority as grounds for halting FTC conduct. *See Official Airlines Guides v. FTC*, 630 F.2d 920 (2d Cir. 1980); *Boise Cascade Corp. v. FTC*, 637 F.2d 573 (9th Cir. 1980); *Ethyl Corp. v. FTC*, 729 F.2d 128 (2d Cir. 1984).

[46] FTC cites *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), but ignores *Credit Suisse* and other more recent Supreme Court authorities making clear that conflict analysis is far broader. *See Carcieri v.*

The issue in *Credit Suisse* was whether a plaintiff could file antitrust claims against investment banks that had formed syndicates and engaged in other practices to form markets for initial public offerings that were actively regulated under the securities laws. 551 U.S. at 269-70. The Supreme Court applied a four-factor test to determine whether such incompatibility existed:

> [I]n finding sufficient incompatibility to warrant an implication of preclusion, have treated the following factors as critical: (1) the existence of regulatory authority under the securities law to supervise the activities in question; (2) evidence that the responsible regulatory entities exercise that authority; and (3) a resulting risk that the securities and antitrust laws, if both applicable, would produce conflicting guidance, requirements, duties, privileges, or standards of conduct . . .. We also note (4) in *Gordon* and *NASD* the possible conflict affected practices that lie squarely within an area of financial market activity that the securities law seeks to regulate.

Credit Suisse, 551 U.S. at 275-76. These factors support finding that HIPAA regulation of data security is incompatible with FTC over-regulation. HIPAA directly applies and delegates rulemaking and standard setting authority to HHS.[47] HHS has adopted data privacy and data security rules, which it routinely

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Salazar, 555 U.S. 379, 395 (2009) (even absent a clearly expressed congressional intention, where two statutes irreconcilably conflict, the more recent statute controls). Interestingly, the LabMD Order recognizes *Credit Suisse* controls. *See* Verified Compl. Ex. 2 at 12-13.

[47] *See* n.1 *supra.*

enforces.[48] The rules address the same activities that are the subject of the FTC enforcement action.

Third, dual enforcement is resulting in (and will continue to result in) conflicting guidance and requirements. The best illustration of conflict is that LabMD's compliance with the HIPAA regulations is not a defense to FTC. Rather, FTC deems regulatory compliance to be to be irrelevant to, much less a defense against, Section 5 unfairness claims. This disdain creates inherent conflict and confusion among HIPAA-regulated businesses.

LabMD submits a declaration from Mr. Baker, who routinely provides advice and consultation to HIPAA-regulated medical service providers. Mr. Baker has reviewed an expert report by Professor Hill that was submitted on behalf of FTC enforcement counsel in the FTC administrative proceedings. Mr. Baker states that the security program described in the FTC expert report conflicts with HIPAA regulations and would cause confusion. Specifically, Mr. Baker noted the FTC expert report required some form of encryption, whereas encryption was considered, but rejected in the HIPAA regulations. A second concern Mr. Baker raised was the absence of scalability, which is a key aspect of HIPAA regulation. Mr. Baker has opined that the conflict between the FTC

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[48] *See* n.1 *supra.*

expert report and HIPAA regulations would confuse HIPAA-regulated entities over the scope of an acceptable data security program.[49]

Fourth, as noted, data security is an area that HIPAA specifically addresses and does so through express statutory authority. As noted above, Congress and HHS have adopted a set of data security requirements that differ in material ways from the FTC's program, requirements for action with regard to some security issues and requirements to document choices regarding other security issues, all through a balancing of interests in the contexts both of legislation and of notice and comment rulemaking. For example, HHS is required by the HIPAA statute to address "the needs and capabilities of small health care providers,"[50] and in the preamble to the HIPAA Security Rule, HHS emphasizes that the Rule must be "scalable, so that it can be effectively implemented by covered entities of all types and sizes,"[51] and notes further that "[s]ince no comprehensive, scalable, and technology-neutral set of standards currently exists, we proposed to designate a new standard, which would define the security requirements to be fulfilled."[52]

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49 Baker Decl. ¶¶ 11-12.

50 42 U.S.C. § 1320d–2(d)(1)(A)(v).

51 68 Fed. Reg. 8,334, 8,335 (Feb. 20, 2003) (Health Insurance Reform: Security Standards).

52 *Id*. 8,341.

FTC, through its designated expert Professor Hill, ignores scalability as a pertinent factor in a lawful data security program.[53]

The Court also noted recent legislation by Congress trying to limit securities lawsuits. Those statutory goals would be circumvented if the same claims could be dressed as an antitrust lawsuit. Likewise, Congress has acted in the field of data security, but has refused to authorize FTC to over-regulate HIPAA-regulated medical services providers.

FTC offers a recent decision by Judge Salas of the United States District Court for the District of New Jersey in a matter styled as *FTC v. Wyndham Worldwide Corp.*, No. 13-1887 (ES) (D.N.J. Apr. 7, 2014) (*"Wyndham")* to support its arguments that LabMD cannot succeed on the merits.[54] The *Wyndham* case is distinguishable. In an enforcement action initiated by FTC, Wyndham challenged whether FTC had *any* authority to regulate data security beyond the express authority delegated to the Commission in several statutes, including HIPAA and HITECH, which address data security regulation. Wyndham is not regulated by any of those statutes. Judge Salas rejected those arguments finding

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53 Baker Decl. ¶¶ 11-12.

54 *See* Dkt. No. 13-9.

that 15 U.S.C. § 45 empowered FTC to address unfair or deceptive practices in the field of data security.[55]

Judge Salas did not address over-regulation or over-filing by FTC, which is the central issue here. *Wyndham* does not imply that FTC may over-regulate HIPAA-regulated medical service providers and engage in "common law" enforcement without disclosing to medical providers what additional data security requirements applied. *Wyndham* thus has no bearing on the issues in this lawsuit.

In sum, the same type of confusion to HIPAA-regulated medical service providers and physicians is occurring because of FTC over-regulation. LabMD does not know what requirements it must meet, FTC will not provide that information, and without assurances that LabMD has a legally sufficient data security program, physicians have taken their needs for cancer-detection services to other laboratories.

3. FTC Has Denied LabMD Due Process.

FTC says LabMD does not have a cognizable liberty or property interest worthy of due process protection. FTC Br. at 32.[56] It also says Section 5 alone is all the fair notice LabMD obtains under the constitution. In both cases, FTC errs.

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[55] 15 U.S.C. § 45(a).

[56] Interestingly, FTC has not taken this position previously or in the *Wyndham* litigation. Thus, this might be a prohibited *post hoc* rationalization for agency

a. LabMD has cognizable constitutional interests.

That LabMD has constitutionally cognizable liberty and property interests here is settled law and not a complex question.

First, FTC admits (as it must) that due process applies in its administrative proceedings. FTC Br. at 37-38; *Withrow v. Larkin*, 421 U.S. 35, 46 (1975) (license-revocation procedures were addressed and court noted process requirements "appl[y] to administrative agencies which adjudicate as well as to courts") (citation omitted).

Second, if FTC may lawfully over-regulate HIPAA regulations, and if LabMD had fair notice, and if FTC finds against LabMD on the record (which is a statistical certainty), then LabMD will be compelled to act and subject to an array of burdensome financial requirements.[57] FTC typically reserves the right to order or seek additional relief as it sees fit, including "restitution," rescission or

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action. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

[57] FTC seeks an order imposing a twenty (20) year obligation to implement whatever data-security measures FTC deems proper, to pay for an initial third-party data-security assessment and report, to pay for updated assessments and reports every two years; to provide FTC-approved notice to thousands of individuals; deliver FTC's order to a wide variety of individuals and businesses; to notify FTC in writing at least thirty (30) days before changing its business practices; and to prepare and file detailed reports with FTC at regular intervals. Verified Compl., ¶ 124 & Ex. 4 at 7-13.

reformation of contracts, and payment of monetary damages.[58] Each violation of the order carries up to a $10,000 civil penalty under 15 U.S.C. § 45(l). As a result, LabMD's liberty and property interests are well-settled.[59]

The FTC's authorities are factually distinguishable.[60] Furthermore, its argument that the chain of events leading to a formal cease order is far too attenuated and is factually inaccurate. The evidence is no respondent has prevailed in an administrative case in nearly 20 years.[61] And, even the one outlier FTC cites to prove its fairness was a liability finding. *FTC Br. at* 19 (citing *In re McWane, Inc. et al.*, FTC Docket No. 9351, Opinion of the Commission (Jan. 30,

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[58] Verified Compl., ¶ 125.

[59] *Ga. Pac. Corp. v. Occupational Safety & Health Review Comm'n*, 25 F.3d 999, 1001 (11th Cir. 1994) (due process fair notice requirements apply to $480 administrative citation); *United States v. Chrysler Corp.*, 158 F.3d 1350, 1355-56 (D.C. Cir. 1998) (car recall); *In re Bogese*, 303 F.3d 1362, 1368 (Fed. Cir. 2002) (forfeiture); *PMD Produce Brokerage v. USDA*, 234 F.3d 48, 51 (D.C. Cir. 2000) (license revocation); *Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 619 (D.C. Cir. 2000) (license renewal); *Barnes v. Zaccari*, 669 F.3d 1295, 1303 (11th Cir. 2012) (noting "broad range" of property interests protected by due process)

[60] *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 575 (1972) (not being rehired in one job does not implicate due process); *Reichenberger v. Pritchard*, 660 F.2d 280, 282 (7th Cir. 1981) (due process not implicated by actions of a private minister, and those of "alderperson" and "Madison Common Council" member who sat on an advisory committee); *Clapper v. Amnesty Int'l, USA*, 133 S. Ct. 1138, 1147 (2012) (due process case was not raised over potential government surveillance of plaintiffs).

[61] Verified Compl., ¶ 94.

2014)).[62] Resorting to the FTC's administrative process should not be required where, as here, it is "futile" or "inadequate." *See N.B. by D.G. v. Alachua Cnty. Sch. Bd.*, 84 F.3d 1376, 1379 (11th Cir. 1996).

b. LabMD has been denied fair notice.

FTC claims the Supreme Court agrees the Commission has unbounded "discretion" to enforce Section 5 without regulations, standards, guidance or policies. FTC Br. at 30. But this is not the law. FTC's failure to provide notice beyond Section 5's general prohibition of unfair trade practices precludes it from springing its data-security standards on unsuspecting businesses through an enforcement action years after the fact. *See Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2168 (2012).

A regulatory standard fails to give fair warning if it "'forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.'" *Ga. Pac. Corp.*, 25 F.3d at 1005 (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)). FTC has claimed that Section 5 is all the notice LabMD needs. FTC Br. at 34. Yet Section 5 does not expressly mention data security or specify

[62] McWane recently asked the FTC to stay the order pending judicial review to prevent irreparable harm. Respondent's Application for Stay of Order Pending Review by U.S. Court of Appeals, *In re McWane, Inc. et al.*, FTC Docket No. 9351 (Mar 13, 2014) (LabMD Reply Ex. 1).

standards, as HIPAA regulations do. The statute by itself therefore does not provide constitutionally adequate notice. *See, e.g., Connally*, 269 U.S. at 391-95; *United States v. Hunt*, 526 F.3d 739, 743 (11th Cir. 2008) ("The question of fair warning must begin with the language of the statute itself.").

Even the Commission has recognized the need for notice in addressing the continued validity of an industry consent order, wherein FTC stated:

> Given the severity of the penalties that may attach for violation of a cease and desist order's provisions, the Supreme Court has required the Commission to fashion orders which are sufficiently clear and precise to avoid raising serious questions as to their meaning and application. **Everyone subject to a cease and desist order is constitutionally entitled to know in advance the precise limits of permissible action**.[63]

LabMD submits that the same Due Process notice describing prohibited and compelled conduct required to be incorporated into cease and desist orders also is required in the enforcement action so the target knows and can cure offending conduct. This is basic Due Process owed to every person in the United States.

FTC's authorities are not controlling. For example, FTC relies on *SEC v. Chenery*, 332 U.S. 194 (1947) to excuse its lack of notice. But *Chenery* is not a fair-notice case. Also, SEC did not seek to impose liability for past conduct as FTC does here. *Id.* at 203-04. Finally, fairly read, *Chenery's* admonition that the

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[63] *In the Matter of New Feather Co.*, No. 5840, 1985 WL 668835, at * 2 (FTC July 25, 1985).

function of filling in statutory interstices such as Section 5's unfairness authority, "should be performed, as much as possible, through . . . quasi-legislative promulgation of rules to be applied in the future," *id.* at 202, rebukes FTC. Yet FTC chooses not to hear the message.[64]

Likewise, *Am. Gas Ass'n v. FERC*, 912 F.2d 1496, 1518-19 (D.C. Cir. 1990), did not involve an agency's attempt to impose future liability for past conduct. *Id.* at 1518-19 (noting that FERC "decided not to re-promulgate a generic customer entitlement to CD reduction, choosing instead to approach it case-by-case"), and indeed was not a fair-notice due process case at all.

FTC also tries to expand the holding in *FTC v. Colgate-Palmolive*. *Colgate-Palmolive* was not an "unfairness" case but a "deception" case which do not raise the same type of due process concerns.[65] *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 375-76 (1965) ("The basic question before us is whether it is a deceptive trade practice, prohibited by § 5 of the Federal Trade Commission Act,

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[64] Due Process limits FTC's "discretion" to choose between modes of regulation. *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995) (administrative law has thoroughly incorporated due process fair notice limits); *Fabi Constr. Co. v. Sec'y of Labor*, 508 F.3d 1077, 1088 (D.C. Cir. 2007).

[65] Case-by-case enforcement of the FTC's "deception" Section 5 authority does not raise the same fair notice due process concerns. FTC has explained that "deception" has a well-defined meaning, but "unfairness" does not. *See In re Int'l Harvester Co.*, 104 FTC 949, 1984 WL 565290 (FTC Dec. 21, 1984) ("[U]nfairness is the set of general principles of which deception is a particularly well-established and streamlined subset.").

to represent falsely that a televised test, experiment, or demonstration provides a viewer with visual proof of a product claim, regardless of whether the product claim is itself true.").[66]

FTC asserts that its "common law" approach to data security regulation satisfies due process and argues that dicta in *NW Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77 (1981), supports such a holding. FTC Br. at 34. But *NW* does not involve fair-notice due process. *NW Airlines*, 451 U.S. at 79-80 (question presented was whether employer had federal statutory or common-law right to contribution from unions that bear partially responsible for an employer violations of labor statutes). Also, the "common law" discussed in that case was created by Article III courts, through judicial decisions, over time, and not agency consent orders and Internet postings. S*ee id.* at 86-88.

Moreover, any reasonableness standard FTC might desire to impose must be linked to industry-specific standards — in this case, HIPAA regulations. *Fla. Mach. & Foundry, Inc.*, 693 F.2d at 120 (emphasis added). LabMD, a HIPAA-

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[66] Since *Colgate-Palmolive Co*, Congress has narrowed the scope of the "unfairness" prohibition to curb FTC abuses. J. Howard Beales, III, *The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection*, 22 J. PUB. POL'Y & MKTG. 192, 193 (2003) (former Director of FTC's Bureau of Consumer Protection discussing Congress's efforts to "rein in" FTC "unfairness" abuse) (LabMD Reply Ex. 2).

regulated medical provider, has done this.[67] But FTC's refusal to be bound to those standards means that its actions in this case violate Due Process.[68]

By stating "that failure to maintain reasonable data security measures can constitute an unfair act or practice within the meaning of Section 5," FTC Br. at 35, FTC admits that it denied LabMD due process. *S&H Riggers*, 659 F.2d at 1280-85; *Fla. Mach. & Foundry, Inc.*, 693 F.2d at 120. FTC relies on *Trans Union Corp. v. FTC*, 245 F.3d 809 (D.C. Cir. 2001), for justification. But, *TransUnion* favors LabMD. *TransUnion* involved the targeted the Fair Credit Reporting Act, not the general Section 5, and the company could clarify statutory meaning through FTC's advisory opinion procedures unavailable here.[69] Fair notice was found because of the extremely clear process for clarifying the meaning of the regulation. *Id.* at 818.

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[67] FTC admits LabMD is a HIPAA-covered medical provider. Complaint Counsel's Opposition to LabMD's Motion to Dismiss, 22 n.15 (Nov. 22, 2013) ("HHS published guidance to entities subject to HIPAA, such as LabMD . . . .") (LabMD Reply Ex. 3). Even the LabMD Order makes clear FTC "cannot enforce HIPAA and does not seek to do so." Verified Compl., Ex. 2 at 12.

[68] FTC also cites *Wyndham*. FTC Br. at 29. That case did not involve over-regulation and is factually distinguishable. But even if controlling, *Wyndham* is wrongly decided under controlling Supreme Court and Eleventh Circuit precedent. *See S&H Riggers & Erectors v. Occupational Safety & Health Review Comm'n*, 659 F.2d 1273, 1279 (5th Cir. 1981); *Fla. Mach. & Foundry, Inc. v. OSHRC*, 693 F.2d 119, 120-21 (11th Cir. 1982) (endorsing *S&H Riggers* analysis).

[69] Verified Compl., Ex. 13 at 52:10-11.

FTC also selectively cites dicta in *Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301 (11th Cir. 2009), to claim fair notice. But, under *Harris*, what the FTC has done to LabMD violates fair notice because LabMD could not predict that FTC would over-regulate HIPAA regulations, much less clarify beforehand how FTC would do so. *See id.* at 1310-11 (quotations omitted).[70]

Finally, FTC cites *Alliance for Natural Health U.S. v. Sebelius*, 775 F. Supp. 2d 114 (D.D.C. 2011), for the proposition that "[a]gencies may use broad terms to describe permissible and impermissible conduct" without violating fair notice due process. FTC Br. at 36. Even where broad terms are permissible, they must be published in advance, which FTC has not done.[71] *See id.* at 131. Furthermore, *Sebelius* is factually distinguishable because that case involved a

[70] *Harris* quotes, *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489 (1982), which also supports LabMD. In that case, the Court noted that economic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action. "Indeed, the regulated enterprise may have the ability to clarify the meaning of the regulation by its own inquiry, or by resort to an administrative process." *Id.* at 498. LabMD did consult and comply with the only relevant legislation and regulations in advance yet the FTC over-regulated using Section 5 unfairness authority and without providing LabMD, or anyone else, any way to clarify in advance what Section 5 supposedly forbade or required. Verified Compl., Ex. 13 at 52:10-11.

[71] Verified Compl., Ex. 9 at 10:8-14; Verified Compl., Ex. 14 at 69:22-70:5; Complaint Counsel's Motion to Amend Complaint Counsel's Response to Respondent's First Set of Requests for Admissions, at 4-5 (Responses to RFAs 1 & 2).

pre-enforcement challenge to regulations, not the challenge to *ex post* enforcement of unstated standards at issue here. *Id*. at 116.

C. Both the Balance of Hardships and the Public Interest Weigh in Favor of Issuing a Preliminary Injunction.

When the government is a party, courts merge the third and fourth factors. *Nken v. Holder*, 556 U.S. 418, 435 (2009). In balancing the hardships, the only harm faced by FTC is "the more nebulous, not easily quantified harm of being prevented from enforcing one of its laws." *Odebrecht*, 715 F.3d at 1289. This hardship is not sufficient to defeat LabMD's motion because FTC's alleged "harm is present every time the validity of a [government action] is challenged, and it is far outweighed by the economic harm to [LabMD]" if FTC acts in violation of the APA or engages in *ultra vires* conduct. *Id.*

Similarly, the public interest favors granting the injunction for at least two reasons. First, "the public has no interest in the enforcement of what is very likely an unconstitutional" and unauthorized enforcement action. *Id.* at 1290. Second, pre-enforcement review of the legal questions in this case will assist the FTC Commissioners in determining the scope of their authority, if any, ensuring the final relief is within that authority. Neither the public nor LabMD are served by FTC enforcement action that exceed the Commission's authority.

CONCLUSION

For the reasons stated above, the Court should deny FTC's motion to dismiss and should issue LabMD's preliminary injunction.

Respectfully submitted, this 11th day of April, 2014.

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CERTIFICATION AS TO FONT

In accordance with Local Rule 7.1(D), the undersigned certifies that this brief was prepared with Times New Roman 14, a font and point selection approved by the Court in Local Rule 5.1.

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CERTIFICATE OF SERVICE

This is to certify that, on April 11, 2014, I electronically filed the foregoing **PLAINTIFF'S RESPONSE TO DEFENDANT FTC'S CONSOLIDATED BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** with the Clerk of Court using the CM/ECF system, and served the following by e-mail and U.S. Mail as follows:

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This 11th day of April, 2014.

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