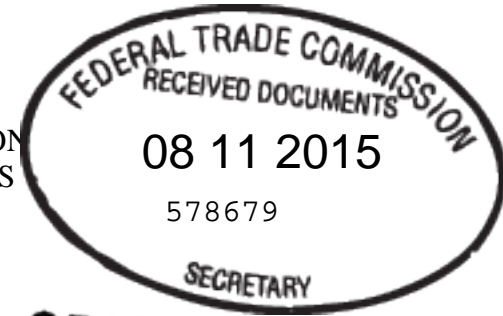


UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION  
OFFICE OF ADMINISTRATIVE LAW JUDGES



\_\_\_\_\_)  
In the Matter of )  
)  
LabMD, Inc. )  
a corporation, )  
Respondent. )  
\_\_\_\_\_)

**PUBLIC**

Docket No. 9357

**ORIGINAL**

**RESPONDENT LABMD, INC.'S**  
**CORRECTED<sup>1</sup> PROPOSED CONCLUSIONS OF LAW**

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Dated: August 11, 2015

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<sup>1</sup> This document was timely filed on August 10, 2015. It is being re-filed solely to correct an error in the document due to the inadvertent inclusion of the watermark "Confidential" in yesterday's filing. Counsel for LabMD has been in constant discussion with Complaint Counsel as well as Crystal McCoy Hunter in the Office of the Secretary regarding these issues.

I. STIPULATIONS OF LAW

1. The acts and practices of Respondent LabMD, Inc. (“LabMD”) alleged in the Complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

2. The patients of LabMD’s physician clients are “consumers” as that term is used in Section 5(n) of Federal Trade Commission Act, 15 U.S.C. § 45(n).

3. Respondent is accused of violating 15 U.S.C. § 45(a), also known as Section 5(a) of the Federal Trade Commission Act.

4. An unfair practice is defined as one that “causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition,” 15 U.S.C. § 45(n).

5. Complaint Counsel has the burden of proof, except as to factual propositions put forward by another proponent, such as affirmative defenses. Rule 3.43(a); 5 U.S.C. § 556(d). The standard of proof is preponderance of the evidence. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 157, at \*133-\*35 (F.T.C. Aug. 5, 2009).

6. Complaint Counsel has the burden of proof to prove by a preponderance of the evidence that LabMD’s practices are likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.

7. Complaint Counsel does not seek to enforce the Health Insurance Portability and Accountability Act (“HIPAA”) in this case.

II. THE APPOINTMENTS CLAUSE

8. Federal Trade Commission (“FTC” or “Commission”) administrative law judges (“ALJs”) are “inferior officers” under U.S. Const., art. II., § 2, cl. 2. *Freytag v. Comm’r of Internal Revenue*, 501 U.S. 868, 883 (1991); *Buckley v. Valeo*, 424 U.S. 1, 132 (1976).

9. FTC ALJs must be appointed to their position by “the President alone, by the heads of departments, or by the Judiciary.” *Buckley*, 424 U.S. at 132.

10. FTC ALJs are appointed by the Office of Personnel Management. 16 C.F.R. § 0.14; *see also Office of Administrative Law Judges*, Fed. Trade Comm’n, <https://www.ftc.gov/about-ftc/bureaus-offices/office-administrative-law-judges> (last visited Aug. 9, 2015) (ALJs are “appointed under the authority of the Office of Personnel Management”).

11. Because ALJs are “officers” under the Appointments Clause, the “dual for-cause” removal protection afforded to them by statute is an unconstitutional “multilevel protection.” *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 484, 502 (2010); *see* 5 U.S.C. § 7521(a) (removal action “may be taken” by FTC against an ALJ “for good cause established and determined by the Merit Systems Protection Board”); 5 U.S.C. § 1202(d); 15 U.S.C. § 41 (FTC commissioners removable for cause).

12. As a matter of law, the Appointments Clause has been violated in this case. *See Hill v. SEC*, No. 1:15-cv-01801-LMM, 2015 U.S. Dist. LEXIS 74822, at \*41-\*42 (N.D. Ga. June 8, 2015).

13. Therefore, this case should be dismissed. *Buckley*, 424 U.S. at 132.

III. PREEMPTION

14. An agency may not use a general grant of authority to declare unlawful conduct that is permitted under a later and more specific legislative enactment. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2070-71 (2012); *Credit Suisse Sec. LLC v. Billing*, 551 U.S. 264, 275 (2007).

15. The Commission's Section 5 authority must be viewed in the light of other relevant statutes, "particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *see also FTC v. Nat'l Cas. Co.*, 357 U.S. 560, 562-63 (1958) (superseded by statute) (examination of subsequent statute and its legislative history demonstrates that it limits the FTC's Section 5 regulatory authority).

16. The Department of Health and Human Services ("HHS") has been authorized to regulate medical data security since the 1990s. *See* 42 U.S.C. § 1320d-2(d)(1) ("Security standards for health information").

17. Historically, the Commission has respected HHS' medical company data security authority. HHS states "entities operating as HIPAA covered entities and business associates are subject to HHS' and not the FTC's, breach notification rule." Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act, 78 Fed. Reg. 5,566, 5,639 (Jan. 25, 2013). The Commission agrees. Health Breach Notification Rule, 74 Fed. Reg. 42,962, 42,963 (Aug. 25, 2009)("[T]he Commission received many comments about the need to harmonize the HHS and FTC rules to simplify compliance burdens and create a level-playing field for HIPAA and non-HIPAA

covered entities. Several commenters agreed with the statements in the FTC’s NPRM that (1) HIPAA-covered entities should be subject to HHS’ breach notification rule and not the FTC’s rule; and (2) business associates of HIPAA-covered entities should be subject to HHS’ breach notification rule, but only to the extent they are acting as business associates. Accordingly, the FTC adopts as final the provision that the rule ‘does not apply to HIPAA-covered entities, or to any other entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity’); *id.* at 42,9642 (“HIPAA-covered entities and entities that engage in activities as business associates of HIPAA-covered entities will be subject only to HHS’ rule and not the FTC’s rule . . .”).

18. The evidence in this case, which was not before the Commission when it issued the Order regarding LabMD’s Motion to Dismiss at 18, *In the Matter of LabMD, Inc.*, FTC Dkt. No. 9357 (Jan. 16, 2014) (the “MTD Order”), demonstrates that data security acts and practices admittedly permitted by HHS could be declared unlawful by the Commission through ad hoc adjudication. *RadLAX Gateway Hotel*, 132 S. Ct. at 2070-71; *Billing*, 551 U.S. at 275.

#### IV. APA/§ 57a VIOLATIONS

19. The Commission is bound by the Administrative Procedure Act (“APA”).

20. A consent decree is not binding authority or a legally-cognizable “standard” of agency expectations. *Intergraph Corp. v. Intel Corp.*, 253 F.3d 695, 698 (Fed. Cir. 2001) (consent orders do “not establish illegal conduct”); *Altria Grp., Inc. v. Good*, 555 U.S. 70, 89 n.13 (2008); Jan M. Rybnicek & Joshua D. Wright, *Defining Section 5 of the FTC Act: The Failure Of The Common Law Method And The Case For Formal Agency Guidelines*, 21 Geo. Mason L. Rev. 1287, 1305-06 (2014) (“[T]he Commission does not treat its settlements as precedent, meaning

that past decisions do not necessarily indicate how the agency will apply Section 5 in the future.”).

21. General statements of policy are prospective and do not create obligations enforceable against third parties like LabMD. *See Am. Bus. Ass’n. v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980) (“The agency cannot apply or rely upon a general statement of policy as law because a . . . policy statement announces the agency’s tentative intentions for the future.”) (citation omitted); *see also Wilderness Soc’y v. Norton*, 434 F.3d 584, 595-96 (D.C. Cir. 2006).

22. If FTC truly considers “public statements,” “educational materials,” and “industry guidance pieces” to be enforceable standards or “statements of general policy,” then it necessarily concedes an APA violation. The APA requires agencies to “publish in the Federal Register for the guidance of the public . . . 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).

23. The APA further provides that, except to the extent “that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published.” 5 U.S.C. § 552(a)(1)(E).

24. Therefore, internet postings of “Guides for Business,” links to SANS Institute and NIST publications, and similar materials on the Commission’s official website do not replace Federal Register publication. *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001).

25. The APA bars the Government from enforcing requirements it claims are set forth in the above-described materials absent Federal Register publication. *See* 5 U.S.C. § 552(a).

26. As a matter of law, the APA obligates FTC to “separately state and currently publish in the Federal Register for the guidance of the public . . . *statements of general policy or interpretations of general applicability* formulated and adopted by the agency . . . .” *See* 5 U.S.C. § 552(a)(1)(D) (emphasis added).

27. The APA bars agencies from enforcing statements of general policy and interpretations of general applicability “[e]xcept to the extent that a person has actual and timely notice” by Federal Register publication. *See* 5 U.S.C. § 552(a)(1)(E); *Util. Solid Waste Activities Grp.*, 236 F.3d at 754 (internet notice is not an acceptable substitute for publication in the Federal Register).

28. 15 U.S.C. § 57a(a)(1) authorizes the Commission to prescribe “interpretive rules and general statements of policy” with respect to unfair acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45 (a)(1)), and “rules” which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce (within the meaning of section 45 (a)(1)), except that the Commission shall not have authority to “develop or promulgate any trade rule or regulation with regard to the regulation of the development and utilization of the standards and certification activities pursuant to this section.”

29. The Commission publishes general statements of policy at 16 C.F.R. Part 14, but there is none for medical data security.

30. The Commission publishes guides for business. *See, e.g.*, 16 C.F.R. pt. 251.

31. The Commission publishes trade rules for business. *See, e.g.*, 16 C.F.R. pt. 455.

32. The Commission cites as “standards” in this case materials that have not been published in the Federal Register in violation of 5 U.S.C. § 552(a)(1)(D). *See* Complaint Counsel’s Pre-Trial Brief at 13-14, 18-20, *In the Matter of LabMD, Inc.*, FTC Dkt. 9357 (May 6, 2014) (citations omitted).

33. The Commission has created applied data security standards as if they had been promulgated as a guide or trade rule. *Compare* Fed. Trade Comm’n, “Start With Security,” <https://www.ftc.gov/tips-advice/business-center/guidance/start-security-guide-business> (June 2015); Fed. Trade Comm’n, “Information Compromise and the Risk of Identity Theft: Guidance for Your Business,” <https://www.ftc.gov/tips-advice/business-center/guidance/information-compromise-risk-identity-theft-guidance-your> (June 2004) (directing businesses to preferred contractors); 16 C.F.R. § 14.9 (titled “Requirements concerning clear and conspicuous disclosures in foreign language advertising and sales materials” and warning “[a]ny respondent who fails to comply with [the specified] requirement may be the subject of a civil penalty or other law enforcement proceeding for violating the terms of a Commission cease-and-desist order or rule”); 16 C.F.R. § 453.1 (funeral rule definitions).

34. The Commission’s use of adjudication to set or apply supposedly preexisting medical data security standards that might add to or alter existing APA-promulgated HIPAA regulations or guidance, based on materials not previously published in the Federal Register is an abuse of discretion and contrary to law under the APA. 5 U.S.C. § 552(a)(1)(D).

35. FTC may proceed by adjudication only in cases where it is enforcing discrete violations of existing laws and where the effective scope of the impact of the case will be relatively small and by § 57a procedures if it seeks to change the law and establish rules of widespread application. *Ford Motor Co. v. FTC*, 673 F.2d 1008, 1010-11 (9th Cir. 1981).



36. Adjudication deals with what the law was; rulemaking deals with what the law will be. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring) (citations omitted).

37. The function of filling in the interstices of the FTC Act should be performed, as much as possible, “*through this quasi-legislative promulgation of rules to be applied in the future.*” *See id.*

38. As a matter of law, the Commission’s adjudication is arbitrary and capricious. *Ford Motor Co.*, 673 F.2d at 1010-11 (citation omitted).

39. Due to the communications between Congress and the Commission regarding this case, the APA required Complaint Counsel to place into the record all *ex parte* communications. 5 U.S.C. § 557(d)(1)(A); *Aera Energy LLC v. Salazar*, 642 F.3d 212, 220-22 (D.C. Cir. 2011); *see also United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1213 (D.C. Cir. 1980) (APA prohibits off-the-record communication between agency decision maker and any other person about a fact in issue); *Pillsbury Co. v. FTC*, 354 F.2d 952, 964 (5th Cir. 1966) .

40. Respondent filed motions regarding the disqualification of FTC commissioners on December 17, 2013, April 27, 2015, May 15, 2015, and July 15, 2015, all of which were wrongfully denied as a matter of law.

41. LabMD’s business model offered groundbreaking benefits to doctors and patients, delivering pathology results to doctors electronically at unprecedented speed, allowing them to more quickly tell anxiously waiting patients whether they had cancer and to begin treatment immediately if needed. However, FTC did not submit into evidence a reasoned countervailing benefit analysis as required by law. *FCC v. Fox Television Stations, Inc.*, 556 U. S. 502, 515 (2009) (noting “the requirement that an agency provide reasoned explanation for its action”).

42. If the Commission exercised enforcement authority based on information that Tiversa provided, notwithstanding Tiversa's economic interest therein, and without independent verification that Tiversa's information was accurate, then it violated the APA. *XP Vehicles, Inc. v. DOE*, 2015 U.S. Dist. LEXIS 90998, \*94-\*100 (D.D.C. July 14, 2015) (court held that a plaintiff alleging adverse government action taken against it, without clear standards or processes, for the benefit of government cronies, stated a claim for which relief could be granted).

V. COMPLAINT COUNSEL HAS FAILED TO PROVE SECTION 5(n) CAUSATION AND SUBSTANTIAL INJURY

A. Construction of Section 5: General Principles

43. “[T]he Commission has only such jurisdiction and authority as Congress has conferred upon it by the Federal Trade Commission Act.” *Cnty. Blood Bank v. FTC*, 405 F.2d 1011, 1015 (8th Cir. 1969) (citations omitted).

44. FTC exercises only Congressionally-delegated administrative functions and not judicial powers. *FTC v. Eastman Kodak*, 274 U.S. 619, 623 (1927).

45. Section 5, titled “Unfair methods of competition unlawful; prevention by Commission,” must be construed not only by reference to the language itself, but also by “the specific context in which that language is used, and the broader context of the statute as a whole.” *Yates v. United States*, 135 S. Ct. 1074, 1081-83 (2015) (construing term “tangible object” in 18 U.S.C. § 1519 in broader context of Sarbanes-Oxley and noting section title and placement, so §1519 was read to cover only tangible objects “one can use to record or preserve information” and not a fish); *see also id.* at 1090 (Alito, J., concurring) (“[M]y analysis is influenced by §1519’s title . . . . Titles can be useful devices to resolve ‘doubt about the meaning of a statute.’”) (citations omitted).

46. “[B]oth [§ 7 of the Clayton Act and § 5 of the Federal Trade Commission Act] were enacted by the 63d Congress, and both were designed to deal with closely related aspects of the same problem – the protection of free and fair competition in the Nation’s marketplaces.” *United States v. Am. Bldg. Maintenance Indus.*, 422 U.S. 271, 277 (1975).

47. For FTC to lawfully exercise its Section 5 unfairness authority (as limited by Section 5(n)) against a given act or practice, it must prove that the targeted act or practice has a generalized, adverse impact on competition or consumers and connect to the “protection of free and fair competition in the Nation’s markets.” *See Yates*, 135 S. Ct. at 1082-83, 1085 (“[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to ‘avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.’”) (citation omitted); *Am. Bldg. Maintenance Indus.*, 422 U.S. at 277; S. Rep. No. 75-221 at 2 (“[W]here it is not a question of a purely private controversy, and where the acts and practices are unfair or deceptive to the public generally, they should be stopped regardless of their effect upon competitors. This is the sole purpose and effect of the chief amendment of section 5.”); J. Howard Beales, Former Dir., Fed. Trade Comm’n, Speech: The FTC’s Use of Unfairness Authority: Its Rise, Fall, and Resurrection, at § II (May 30, 2003) (“The Commission . . . is now giving unfairness a more prominent role as a powerful tool for the Commission to analyze and attack a wider range of practices that may not involve deception but nonetheless cause *widespread and significant consumer harm*”) (emphasis added), available at <https://www.ftc.gov/public-statements/2003/05/ftcs-use-unfairness-authority-its-rise-fall-and-resurrection>; Hon. Julie Brill, Comm’r, Fed. Trade Comm’n, Responses to Sen. Kelly Ayotte (QFR), U.S. S. Comm. on Commerce, Sci. & Transp.: Privacy and Data Security: Protecting Consumers in the Modern

World at 223 (June 19, 2011), *available at* [http://www.governmentattic.org/13docs/FTC-QFR\\_2009-2014.pdf](http://www.governmentattic.org/13docs/FTC-QFR_2009-2014.pdf) (“*The Commission will not bring a case where the evidence shows no actual or likely harm to competition or consumers.* As the Chairman explained in his testimony before the Senate Judiciary Committee last summer, ‘Of (*sic*) course, *in using our Section 5 authority the Commission will focus on bringing cases where there is clear harm to the competitive process and to consumers.*’ *That is, any case the Commission brings under the broader authority of Section 5 will be based on demonstrable harm to consumers or competition.*”) (emphasis added).

48. Section 5(n) provides: “The Commission lacks authority to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and is not outweighed by countervailing benefits to consumers or to competition.” 15 U.S.C. § 45(n).

49. Section 5’s language “implies the enactment of a standard of proof.” *See Steadman v. SEC*, 450 U.S. 91, 98 (1981).

50. Section 5(n) was enacted to cabin, not expand, the Commission’s use of unfairness authority and should be construed accordingly. *See* S. Comm. Rep. 103-130, FTC Act of 1993 (Aug. 24, 1993) (stating that “[t]his section amends section 5 of the FTC Act to limit unlawful ‘unfair acts or practices’ to only those which cause or are likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition” and that “substantial injury” is “not intended to encompass merely trivial or speculative harm”); Statement of Rep. Moorehead, Congressional Record Volume 140, Number 98 (Monday, July 25, 1994) (“Taken as

a whole, these new criteria defining the unfairness standard should provide a strong bulwark against potential abuses of the unfairness standard by an overzealous FTC--a phenomenon we last observed in the late 1970's"); Beales, *supra* at § II (former Director of FTC's Bureau of Consumer Protection describing how Congress "reigned in" Commission "abuse" of its Section 5 unfairness authority).

51. The operative terms in Sections 5(a) and 5(n), including "unfair" and "likely," are undefined. The Commission has not promulgated definitional regulations or guidance. Therefore, a common meaning construction is proper. *FDIC v. Meyer*, 510 U.S. 471, 477 (1994).

52. Webster's primary definition of "unfair" is "marked by injustice, partiality, or deception: unjust." *See* Merriam-Webster's Dictionary, <http://www.merriam-webster.com/dictionary/unfair> (last visited Aug. 9, 2015).

53. Webster's primary definition of "likely" is "having a high probability of occurring or being true: very probable (rain is likely today)." *See* Merriam-Webster's Dictionary, <http://www.merriam-webster.com/dictionary/likely> (last visited Aug. 9, 2015).

54. The Ninth Circuit has defined "likely" as "probable." *See Sw. Sunsites v. FTC*, 785 F.2d 1431, 1436 (9th Cir. 1985). Webster's defines "probable" to mean "supported by evidence strong enough to establish presumption but not proof." Merriam-Webster's Dictionary, <http://www.merriam-webster.com/dictionary/probable> (last visited Aug. 9, 2015).

55. Section 5(a)'s common meaning requires Complaint Counsel to allege and prove by a preponderance of the evidence that the data security acts and practices identified in the Complaint were "unfair" – that is, marked by injustice, partiality, or deception. *See* 15 U.S.C. §§ 45(a), (n); *Yates*, 135 S. Ct. at 1081-83, 1091; Hearings, 16 C.F.R. § 3.43; Merriam-Webster's

Dictionary, <http://www.merriam-webster.com/dictionary/unfair> (last visited Aug. 9, 2015).

However, it has not done so and therefore judgment for the Respondent is appropriate.

56. Section 5(n)'s common meaning verb tense requires Complaint Counsel to prove by at least a preponderance of the evidence that each given act or practice "causes" in the present or is "likely to cause" in the future substantial injury to consumers. 15 U.S.C. § 45(n); 1 U.S.C. § 1 (words used in the present tense include the future as well as the present); *Carr v. United States*, 560 U.S. 438, 448 (2010) ("Consistent with normal usage, we have frequently looked to Congress' choice of verb tense to ascertain a statute's temporal reach" and "[b]y implication, then, the Dictionary Act [1 U.S.C. § 1] instructs that the present tense generally does not include the past"); *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.*, 484 U.S. 49, 57 (1987) ("Congress could have phrased its requirement in language that looked to the past . . . , but it did not choose this readily available option"); *Steadman*, 450 U.S. at 98.

57. Section 5(n)'s common meaning verb tense does not authorize the Commission to declare unfair and unlawful a past act or practice because a statute's "undeviating use of the present tense" is a "striking indic[ator]" of its "prospective orientation." 15 U.S.C. § 45(n); 1 U.S.C. § 1; *Carr*, 560 U.S. at 44; *Gwaltney*, 484 U.S. at 59.

58. Even if Section 5, as cabined by Section 5(n), authorizes the Commission to reach past acts or practices, Section 5(n), based on the ordinary meaning of its language and verb tense, prevents it from declaring an act or practice unfair and unlawful and issue a cease and desist order unless Complaint Counsel proves by at least a preponderance of the evidence that each challenged act or practice is "likely" (*i.e.*, probable or highly probable) to reoccur and then "likely to cause" substantial consumer injury. 15 U.S.C. §45(n); *Carr*, 560 U.S. at 448-49; *Gwaltney*, 484 U.S. at 59; *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("The

purpose of an injunction is to prevent future violation and, of course, it can be utilized even without a showing of past wrongs. But . . . [t]he necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.”) (citation omitted); *Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110-11 (2d Cir. 1984) (holding FTC failed to bear its burden and justify relief because “speculative and conjectural” allegations were not sufficient to justify equitable relief against a terminated violation); *Litton Indus., Inc. v. FTC*, 676 F.2d 364, 370 (9<sup>th</sup> Cir. 1982) (the “ultimate question is the likelihood of the petitioner committing the sort of unfair practices they prohibit” in the future).

59. Section 5 remedies are prospective and preventative rather than compensatory, punitive, or structural. *See* 15 U.S.C. § 45(b) (authorizing cease and desist order); *Riordan v. SEC*, 627 F.3d 1230, 1234 (D.C. Cir. 2010) (“[A] cease-and-desist order is ‘purely remedial and preventative’ and not a ‘penalty’ or ‘forfeiture.’”) (citing *Drath v. FTC*, 239 F.2d 452, 454 (D.C. Cir. 1956)).

60. As a matter of law, Complaint Counsel must prove by a preponderance of the evidence that the allegedly unfair and unlawful data security acts and practices identified in the Complaint are unfair to consumers generally and/or affected enough consumers to implicate or affect free and fair competition in the market generally. 15 U.S.C. §§ 45(a), (n); *Yates*, 135 S. Ct. at 1085, 1091; *Am. Bldg. Maintenance Indus.*, 422 U.S. at 277; Hearings, 16 C.F.R. § 3.43 (2015); Beales, *supra* (unfairness authority is “a powerful tool for the Commission” to attack a particular Respondent’s practices “that may not involve deception but nonetheless cause *widespread and significant consumer harm*”) (emphasis added).

B. Burden of Proof: Standard

61. This Court serves as fact-finder and Complaint Counsel is not entitled to any favorable inferences. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062-65, 1170 (11th Cir. 2005).

62. Complaint Counsel bears the burden of proving each element of its case by a preponderance of the evidence. *In re N.C. Bd. of Dental Exam'rs*, No. 9343, 2011 FTC LEXIS 137, \*10-\*11 (F.T.C. July 14, 2011); Hearings, 16 C.F.R. § 3.43.

63. The preponderance of evidence standard applied by the Commission in this case arguably conflicts with a common-meaning construction of Section 5(n) with respect to acts or practices that are alleged unfair and unlawful due to the risk of future substantial consumer injury. *See* 15 U.S.C. § 45(n); *Steadman*, 450 U.S. at 98; Hearings, 16 C.F.R. § 3.43.

64. Because Section 5(n) uses the phrase “likely to cause” Complaint Counsel should be required to meet the clear and convincing burden of proof with respect to future injury. 15 U.S.C. § 45(n); *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (describing clear and convincing standard); *Steadman*, 450 U.S. at 98 (statutory language creates standard of proof).

C. Causation

65. Section 5 and Section 5(n) must be construed based on ordinary meaning. *Meyer*, 510 U.S. at 477.

66. Section 5(n) was enacted to limit FTC’s abuse of its unfairness authority and should be construed accordingly. *See Yates*, 135 S.Ct. at 1082-85, 1091; S. Com. Rep. 103-130, FTC Act of 1993 (Aug. 24, 1993); Statement of Rep. Moorehead, Congressional Record Volume 140, Number 98 (Monday, July 25, 1994); Beales, *supra* at § II (Congress “reigned in” Commission “abuse” of Section 5 unfairness authority).



67. As a matter of law, Complaint Counsel was required to allege and prove by a preponderance of the evidence that the data security acts and practices identified in the Complaint were “unfair” – that is, marked by injustice, partiality, or deception. *See* 15 U.S.C. §§ 45(a), (n); *Yates*, 135 S. Ct. at 1081-83, 1091; *Carr*, 560 U.S. at 44; *Meyer*, 510 U.S. at 477; Hearings, 16 C.F.R. § 3.43; Merriam-Webster’s Dictionary, <http://www.merriam-webster.com/dictionary/unfair> (last visited Aug. 9, 2015). Complaint Counsel has not done so and judgment for Respondent should be granted.

68. As a matter of law, Complaint Counsel must allege and prove by a preponderance of the evidence that the unfair and unlawful data security acts and practices identified in the Complaint are unfair to consumers generally and/or affected enough consumers to implicate or affect free and fair competition in the market generally. 15 U.S.C. §§ 45(a), (n); *Yates*, 135 S. Ct. at 1085, 1091; *Am. Bldg. Maintenance Indus.*, 422 U.S. at 277; Hearings, 16 C.F.R. § 3.43;; Beales, *supra* (unfairness authority is “a powerful tool for the Commission” to attack a particular Respondent’s practices that “cause *widespread and significant consumer harm*”) (emphasis added). Complaint Counsel has not done so and judgment for Respondent is proper as a matter of law.

69. Complaint Counsel must prove by a preponderance of the evidence that each of the allegedly unfair and unlawful acts or practices identified in the Complaint currently “causes” or is “likely to cause” substantial injury to consumers. *See* 15 U.S.C. § 15(n); 1 U.S.C. § 1; *Carr*, 560 U.S. at 448; *Gwaltney*, 484 U.S. at 57; *Steadman*, 450 U.S. at 98; Compl. ¶ 22 (“As set forth in Paragraphs 6 through 21, respondent’s [*sic*] failure to employ reasonable and appropriate measures to prevent unauthorized access to personal information . . . *caused, or is likely to cause*, substantial injury to consumers . . . .”) (emphasis added).

70. The plain language of Section 5(n) does not authorize the Commission to declare past conduct unfair and unlawful and, because Complaint Counsel has failed to prove by a preponderance of the evidence that any of the challenged acts or practices occurred after 2010, judgment for Respondent is appropriate as a matter of law. 15 U.S.C. § 45(n); 1 U.S.C. § 1; *Carr*, 560 U.S. at 448; *Meyer*, 510 U.S. at 477; *Gwaltney*, 484 U.S. at 59; *W. T. Grant Co.*, 345 U.S. at 633; *Borg-Warner Corp.*, 746 F.2d at 110-11.

71. If Section 5(n) allows the Commission to declare past acts or practices unfair and unlawful, then Complaint Counsel must show by a preponderance of the evidence that such acts or practices are “likely to cause” substantial consumer injury in the future. *See* 15 U.S.C. § 15(n). Complaint Counsel does allege that the acts or practices identified in the Complaint are “likely to cause” substantial injury in the future. However, Complaint Counsel has failed to prove by a preponderance of the evidence that the allegedly unfair and unlawful acts or practices are “likely” to reoccur. Consequently, judgment for Respondent as a matter of law is appropriate. *See* 15 U.S.C. § 15(n); 1 U.S.C. § 1; *Carr*, 560 U.S. at 448; *Meyer*, 510 U.S. at 477; *Gwaltney*, 484 U.S. at 59; *W. T. Grant Co.*, 345 U.S. at 633; *Borg-Warner Corp.*, 746 F.2d at 110-11; *see also WHX v. SEC*, 362 F.3d 854, 861 (D.C. Cir. 2004) (“WHX committed (at most) a single, isolated violation of the rule, it immediately withdrew the offending condition once the Commission had made its official position clear, and the Commission has offered no reason to doubt WHX’s assurances that it will not violate the rule in the future. In light of these factors, none of which the Commission seems to have considered seriously, the imposition of the cease-and-desist order seems all the more gratuitous”); *see also FTC v. Colgate-Palmolive Co., et al.*, 380 U.S. 374, 920 (1965) (“In this case the respondents produced three different commercials which employed the same deceptive practice. This we believe gave the Commission a sufficient

basis for believing that the respondents would be inclined to use similar commercials with respect to the other products they advertise.”); *NLRB v. Express Publ’g*, 312 U.S. 426, 436-37 (1941).

D. Substantial Injury

72. Section 5(n) requires Complaint Counsel to prove that a challenged act or practice is “likely” (probable) to cause “substantial injury” to consumers that is not reasonably avoidable by them or outweighed by countervailing benefits. 15 U.S.C. § 45(n); *Meyer*, 510 U.S. at 477.

73. “The Commission is not concerned with trivial or merely speculative harms.” Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (Dec. 17, 1980), *reprinted in In re Int’l Harvester Co.*, 104 F.T.C. 949, 1984 FTC LEXIS 2, at \*308-\*09 (F.T.C. Dec. 21, 1984) (emphasis added); *accord Reilly v. Ceridian Corp.*, 664 F.3d 38, 44-46 (3d Cir. 2011); Beales, *supra* (unfairness authority aimed at “widespread and significant consumer harm”) (emphasis added).

74. FTC’s Policy Statement on Unfairness provides that “[i]n most cases a substantial injury involves monetary harm, as when sellers coerce consumers into purchasing unwanted goods or services or when consumers buy defective goods or services on credit but are unable to assert against the creditor claims or defenses arising from the transaction.” Fed. Trade Comm’n, *FTC Policy Statement on Unfairness*, <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness> (last visited August 9, 2015).

75. As a matter of law, Complaint Counsel must allege and prove by a preponderance of the evidence that the allegedly unfair and unlawful data security acts and practices identified in the Complaint to cause substantial consumer injury are unfair to consumers generally and/or affected enough consumers to implicate or affect free and fair competition in the market

generally. 15 U.S.C. §§ 45(a), (n); Hearings, 16 C.F.R. § 3.43 (2015); *Yates*, 135 S. Ct. at 1085, 1091; *Am. Bldg. Maintenance Indus.*, 422 U.S. at 277; Beales, *supra* (unfairness authority is “a powerful tool for the Commission” to attack a particular Respondent’s practices “that may not involve deception but nonetheless cause *widespread and significant consumer harm*”) (emphasis added).

76. Established judicial principles help FTC “ascertain whether a particular form of conduct does in fact tend to harm consumers.” *In re Int’l Harvester Co.*, 1984 FTC LEXIS 2, at \*313 (citation omitted).

77. To prove “substantial injury” in this case as a matter of law, Complaint Counsel must first prove *both* actual data breaches *and* that LabMD’s data security practices were “unreasonable” for medical companies during the relevant time frame. *See* 15 U.S.C. § 45(n); *Fabi Const. Co. v. SOL*, 508 F.3d 1077, 1088 (D.C. Cir. 2007) (industry standards for building construction company applied); *Ensign-Bickford Co. v. OSHRC*, 717 F.2d 1419, 1422 (D.C. Cir. 1983) (industry standards for pyrotechnic industry applied); *S&H Riggers & Erectors v. OSHRC*, 659 F.2d 1273, 1280-83 (5th Cir. 1981) (reasonable-person standard divorced from relevant industry standards or regulations violates due process); MTD Order at 18.

78. As a matter of law, proof of an actual data breach is a necessary but not sufficient condition for “substantial injury” as a matter of law under Section 5(n). According to the Commission:

Notably, the Complaint’s allegations that LabMD’s data security failures led to actual security breaches, if proven, would lend support to the claim that the firm’s data security procedures caused, or were likely to cause, harms to consumers – but the mere fact that such breaches occurred, standing alone, would not necessarily establish that LabMD engaged in ‘unfair . . . acts or practices.’ . . . [T]he mere fact that data breaches actually occurred is not sufficient to show a company failed to have reasonable “we will need to determine whether the ‘substantial injury’ element is satisfied by considering not only whether the facts [of actual data breaches] alleged in the Complaint actually occurred but

also whether LabMD's data security procedures were 'reasonable' in light of the circumstances.

MTD Order at 18-19 (citations omitted); *cf. FTC v. Wyndham Worldwide Corp.*, 10 F. Supp. 3d 602, 609 (D. N.J. 2014) (FTC alleged three actual data breaches leading to "the compromise of more than 619,000 consumer payment card account numbers, the exportation of many of those account numbers to a domain registered in Russia, fraudulent charges on many consumers' accounts, and more than \$10.6 million in fraud loss. Consumers and businesses suffered financial injury, including, but not limited to, unreimbursed fraudulent charges, increased costs, and lost access to funds or credit. Consumers and businesses also expended time and money resolving fraudulent charges and mitigating subsequent harm.").

79. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that either of the Security Incidents alleged in the Complaint constituted an actual data breach. *See* MTD Order at 18-19; *Wyndham*, 10 F. Supp. 3d at 609.

80. Speculation about possible identity theft and fraud does not satisfy Section 5(n)'s substantial injury requirement as a matter of law. *See* Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (Dec. 17, 1980), *reprinted in In re Int'l Harvester Co.*, 1984 FTC LEXIS 2, at \*308-\*09 (emphasis added); *accord Reilly*, 664 F.3d at 44-46; *cf. Wyndham*, 10 F. Supp. 3d at 609.

81. Established judicial principles suggest "substantial injury" under Section 5(n) must at least be more than an "injury in fact," that is, the invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). While the test for constitutional standing is low, *see, e.g., Blunt v. Lower Marion Sch. Dist.*, 767 F.3d 247, 278 (3rd Cir. 2014) (requiring only "some specific, identifiable trifle of injury"), Section 5(n) contains

two additional requirements: the injury must be (1) “substantial,” which, to have any meaning, must be something more than the injury required by Article III; and, (2) not “reasonably avoidable by consumers themselves.” 15 U.S.C. § 45(n).

82. In data breach cases where no misuse is proven there has been no injury as a matter of law. *Reilly*, 664 F.3d at 44.

83. An “injury” is not actionable under Section 5(n) “if consumers are aware of, and are reasonably capable of pursuing, potential avenues toward mitigating the injury after the fact.” *Davis v. HSBC Bank Nevada*, 691 F.3d 1152, 1168-69 (9th Cir. 2012). The issue “not whether subsequent mitigation was convenient or costless, but whether it was reasonably possible.” *Id.* at 1169. As a matter of law, speculation about the potential time and money consumers could spend resolving fraudulent charges cannot satisfy Section 5(n), or even confer standing under Article III. *See id.*; *Reilly*, 664 F.3d at 46 (alleged time and money expenditures to monitor financial information do not establish standing, “because costs incurred to watch for a speculative chain of future events based on hypothetical future criminal acts are no more ‘actual’ injuries than alleged ‘increased risk of injury’ claims”); *Randolph v. ING Life Ins. & Annuity Co.*, 486 F. Supp. 2d 1, 8 (D.D.C. 2007) (“[L]ost data” cases “clearly reject the theory that a plaintiff is entitled to reimbursement for credit monitoring services or for time and money spent monitoring his or her credit.”) (citation omitted). That a plaintiff has willingly incurred costs to protect against an alleged increased risk of identity theft is not enough to demonstrate a “concrete and particularized” or “actual or imminent” injury. *In re Sci. Applications Int’l Corp. (SAIC) Backup Tape Data Theft Litig.*, 45 F. Supp. 3d 14, 28-33 (D.D.C. May 9, 2014) (listing cases).

## VI. LEGAL STANDARDS FOR “REASONABLENESS”

84. Complaint Counsel must prove by a preponderance of the evidence that there was an actual data breach *and*, if one occurred, that consumers suffer substantial injury *and* that LabMD's data security practices are "unreasonable." *See* MTD Order at 18-19; *HSBC Bank Nevada*, 691 F.3d at 1169; *Reilly*, 664 F.3d at 44-46.

85. The Commission states "unreasonableness" is a "factual question that can be addressed only on the basis of evidence" but provides no additional guidance. MTD Order at 19.

86. Medical data security "reasonableness" under Section 5 as a matter of law is a matter of first impression.

87. Section 5(n) does not define "unreasonable" data security acts or practices, or even use the term. Therefore, there is no statutory basis for a "reasonableness" determination. *See Steadman*, 450 U.S. at 98. However, the MTD Order, though erroneous, is law of the case.

88. As a matter of law, FTC does not have the power to declare – for the first time through adjudication – conduct that is permitted by and compliant with HHS's preexisting regulatory scheme, promulgated under HIPAA/HITECH in accordance with an act of Congress, unfair and unlawful under Section 5(n). *See Fabi Const. Co.*, 508 F.3d at 1088; *ABA v. FTC*, 430 F.3d 457, 469-72 (D.C. Cir. 2005); *Satellite Broad. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987); *Gates & Fox v. OSHRC*, 790 F.2d 154, 156-57 (D.C. Cir. 1986); Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5,566, 5,644 (Jan. 25, 2013) (encouraging covered entities to use encryption safe-harbor); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,543 (Dec. 28, 2000) (discussing safe-harbor).

89. As a matter of law, FTC should have published in the Federal Register applicable guides or policy statements prior to commencing regulation, as it has often done. *See* 16 C.F.R. § 14.9 (titled “Requirements concerning clear and conspicuous disclosures in foreign language advertising and sales materials,” establishing same and warning “[a]ny respondent who fails to comply with [the specified] requirement may be the subject of a civil penalty or other law enforcement proceeding for violating the terms of a Commission cease-and-desist order or rule”); 16 C.F.R. § 453.1 (funeral rule definitions); *see also* 15 U.S.C. 57a(a).

90. FTC may proceed by adjudication only in cases where it is enforcing discrete violations of existing laws and where the effective scope of the impact of the case will be relatively small and by § 57a procedures if it seeks to change the law and establish rules of widespread application. *Ford Motor Co.*, 673 F.2d 1008, 1010-11 (9th Cir. 1981).

91. Adjudication deals with what the law was; rulemaking deals with what the law will be. *Bowen*, 488 U.S. at 221 (1988) (Scalia, J., concurring).

92. The function of filling in the interstices of the FTC Act should be performed, as much as possible, “*through this quasi-legislative promulgation of rules to be applied in the future.*” *See id.* (emphasis in original).

93. As a matter of law, the Commission’s adjudication is arbitrary and capricious. *Ford Motor Co.*, 673 F.2d at 1010-11 (citation omitted).

94. Complaint Counsel’s failure to prove by a preponderance of the evidence that LabMD’s data security currently violates, or is likely to violate in the future HIPAA/HITECH regulatory requirements, means that it has not proven unreasonableness as a matter of law.

95. A data security hearing under Section 5 is governed solely by the ordinary meaning of Section 5(a) and Section 5(n).



96. Complaint Counsel's position is that "[t]he enforcement of OSHA's General Duty Clause in Department of Labor administrative courts may provide the best analogy to a data security administrative hearing under Section 5 of the FTC Act. *See, e.g., Fabi Construction Co.*, 508 F.3d at 1088 (D.C. Cir. 2007) (considering a number of factors to determine whether defendant met its "general duty," including whether defendant followed third-party technical drawings, whether defendant complied with industry standards, and expert opinion); Complaint Counsel's Response In Opposition to Respondent's Motion to Dismiss Complaint at 19 n.12, *In the Matter of LabMD, Inc.*, FTC Dkt. 9357 (Nov. 22, 2013).

97. Reasonableness is not whatever requirement the Commission determines, *post facto*, to have applied as if it were drafting a regulation. Rather, reasonableness is an objective test which must be determined on the basis of evidence in the record and "industry standards" are concrete and discernible standards applicable to a given company in its particular line of business. *See Fabi Constr. Co.*, 508 F.3d at 1084 (industry standards for a building construction company applied); *Ensign-Bickford Co.*, 717 F.2d at 1422 (industry standards for the pyrotechnic industry applied); *S&H Riggers*, 659 F.2d at 1280-83 (reasonable-person standard divorced from relevant industry standards or regulations violates due process); *Diebold, Inc. v. Marshall*, 585 F.2d 1327, 1333 (6th Cir. 1978) ("[U]nless we embrace the untenable assumption that industry has been habitually disregarding a known legal requirement, we must conclude that the average employer has been unaware that the regulations required point of operation guarding.").

98. LabMD is, as a matter of law, a HIPAA-covered entity and the relevant standards are those in effect for the medical industry and applicable to HIPAA-regulated entities. 45 C.F.R. § 160.103; *Fabi Constr. Co.*, 508 F.3d at 1084; *Ensign-Bickford Co.*, 717 F.2d at 1422;

*S&H Riggers*, 659 F.2d at 1280-83 (reasonable-person standard divorced from relevant industry standards or regulations violates due process); *Diebold, Inc.*, 585 F.2d at 1333.

99. Industry standards and customs are not entirely determinative of reasonableness because there may be instances where a whole industry has been negligent. *See Bristol Steel & Iron Works, Inc. v. OSHRC*, 601 F.2d 717, 723 (4th Cir. 1979) (“[T]he appropriate inquiry is whether under the circumstances a reasonably prudent employer familiar with steel erection would have protected against the hazard of falling by the means specified in the citation.”).

100. However, such negligence on the part of a whole industry cannot be lightly presumed and must be proven. *Diebold*, 585 F.2d at 1333.

101. Applicable medical industry standards were and are readily available. *See* 45 C.F.R. §§ 164.400-414 (breach notification rule); Health Insurance Reform: Security Standards, 68 Fed. Reg. 8344 (Feb. 20, 2003); Fed. Trade Comm’n, “Complying with the FTC’s Health Breach Notification Rule,” <https://www.ftc.gov/tips-advice/business-center/guidance/complying-ftcs-health-breach-notification-rule> (last visited August 9, 2015); Dep’t of Health & Human Servs., “HIPAA Security Series: Security 101 for Covered Entities,” <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/security101.pdf> (last accessed Aug. 9, 2015).

102. LabMD and all other covered entities in the medical industry must follow HIPAA, HITECH, and HHS PHI data security regulations. *See, e.g.*, Applicability of Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R. § 164.302 (“A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.”); 45 C.F.R. § 160.103 (definition of a “covered entity”).

103. LabMD has not violated HIPAA/HITECH. *See* Complaint Counsel’s Amended Response To LabMD, Inc.’s First Set Of Requests For Admission, *In the Matter of LabMD*, Dkt. No. 9357, Responses No. 7 and No. 8, at pp. 8-9, appended to Complaint Counsel’s Motion to Amend Complaint Counsel’s Response to Respondent’s First Set of Requests for Admission (Apr. 1, 2014); *see also* Compl., *In the Matter of LabMD*, Dkt. No. 9357 (Aug. 28, 2013).

104. As a matter of law, it is arbitrary, capricious, contrary to law, and a violation of due process for Complaint Counsel to allege and/or the Commission to determine unreasonableness without specific reference to HIPAA/HITECH standards and regulations. *See Fabi Constr. Co.*, 508 F.3d at 1084; *Ensign-Bickford Co.*, 717 F.2d at 1422; *S&H Riggers*, 659 F.2d at 1280-83.

105. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that the entire medical industry was negligent or that HIPAA/HITECH regulations and standards were or are inadequate. *See Diebold, Inc.*, 585 F.2d at 1336.

106. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD’s compliance with the HIPAA/HITECH regulations and standards causes or is likely to cause substantial harm to consumers.

107. As a matter of law, if Respondent reasonably relied on experts to design and implement its information technology system, then its data security practices cannot be “unreasonable.” *See R.P. Carbone Constr. Co. v. OSHRC*, 166 F.3d 815, 819-20 (6th Cir. 1998) (reasonable reliance on subcontractors who were experts relieves contractor from liability) (citation omitted).

## VII. CONSTITUTIONAL DUE PROCESS VIOLATIONS

108. FTC is constrained by due process. *See Withrow*, 421 U.S. 35, 47 (1975); *FTC v. Am. Tobacco Co.*, 264 U.S. 298, 305-06 (1924). This means that the Fourth Amendment applies. *See generally Gibson v. Berryhill*, 411 U.S. 564, 579 (1973); *Camara v. Mun. Court of San Francisco*, 387 U.S. 523 (1967) (protecting businesses subjected to regulatory searches); *OFCCP v. Bank of Am.*, 97-OFC-16, Admin. Review Bd.’s Decision and Order of Remand (Dep’t of Labor Mar. 31, 2003) (protecting businesses from agency searches).

109. The Commission must maintain the appearance of impartiality, free from the taint of prejudgment. *Pillsbury Co.*, 354 F.2d at 964 (citing *In re Murchison*, 349 U.S. 133, 136 (1955)); *see also United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 267-68 (1954); *Aera Energy LLC*, 642 F.3d at 221 (“[P]olitical pressure invalidates agency action only when it shapes, in whole or in part, the judgment of the ultimate agency decisionmaker.”); *United States v. Fensterwald*, 553 F.2d 231, 232 (D.C. Cir. 1977).

110. The Commission owed LabMD a fair and honest process. *See Maness v. Meyers*, 419 U.S. 449, 463-64 (1975) (Fifth Amendment applies to administrative proceedings); *Nec Corp. v. United States*, 151 F.3d 1361, 1370 (Fed. Cir. 1998); *see also In re Murchison*, 349 U.S. 133, 136 (1955). This rule applies with equal force in administrative proceedings. *See Gibson*, 411 U.S. at 579.

111. “The doctrine that the federal government should not be permitted to avail itself of its own wrongdoing is yet good law.” *Oliva-Ramos v. Att’y Gen. of the United States*, 694 F.3d 259 (3rd Cir. 2012) (the exclusionary rule is permitted in federal administrative proceedings if evidence is obtained as a result of an egregious constitutional violation”); *EEOC v. Red Arrow Corp.*, 392 F. Supp. 64 (E.D. Mo. 1974) (After court was informed EEOC placed a newspaper ad charging defendant with racial discrimination and soliciting plaintiffs/witnesses, it ruled “[s]uch

conduct is wholly and totally reprehensible and is inconsistent with the high standard of conduct required from an officer of the Court. This Court has never and shall never countenance such demeanor on the part of an attorney for to do so would undermine the very bulwarks of our jurisprudential heritage. . . . all fruits of the aforesaid impermissible publication will not be admissible in evidence in this action”); *see generally* Richard M. Re, *The Due Process Exclusionary Rule*, 127 Harv. L. Rev. 1885 (2014) (exclusionary rule is truly a due process rule).

A. FTC/Tiversa Collaboration

112. Due process is offended if Complaint Counsel or its experts are allowed to rely on evidence obtained illegally or wrongfully or on any of the fruits thereof. *Atlantic Richfield Co. v. FTC*, 546 F.2d 646, 651 (5th Cir. 1977); *Knoll Assocs. v. FTC*, 397 F.2d 530, 537 (7th Cir. 1968) (remanding case to FTC with instructions to reconsider without documents and testimony given or produced by or through witness who stole materials from respondent); *see also Communist Party of the United States v. Subversive Activities Control Bd.*, 351 U.S. 115, 125 (1956); *Rochin v. California*, 342 U.S. 165, 172-74 (1952).

113. Complaint Counsel may not use false evidence provided by a deceitful informant in this proceeding. *See Giglio v. United States*, 405 U.S. 150, 153 (1972) (presentation of known false evidence is incompatible with rudimentary demands of justice); *Morris v. Ylst*, 447 F.3d 735, 744 (9th Cir. 2006) (suspected perjury requires an investigation and this “duty to act ‘is not discharged by attempting to finesse the problem by pressing ahead without a diligent and good faith attempt to resolve it’”).

114. Evidence illegally obtained is properly excluded in administrative proceedings. *Marshall v. Barlow’s, Inc.*, 436 U.S. 307 (1978); *Donovan v. Sarasota Concrete Co.*, 693 F.2d 1061 (11th Cir. 1982) (OSHA citation hearing); *United States v. Widow Brown’s Inn of*

*Plumsteadville, Inc.*, 1992 OCAHO LEXIS 3, 44, ALJ's Decision and Order (Dep't of Justice Exec. Office for Immigration Review Jan. 15, 1992).

115. As the court held in *Knoll*:

We hold that we have not only the power but the duty to apply constitutional restraints when pertinent to any proceeding of which we have jurisdiction, such as a statutory review of a federal commission decision. At stake here is the ordered concept of liberty of which Mr. Justice Holmes spoke in his dissenting opinion in *Olmstead v. United States*, 'apart from the Constitution the Government ought not to use evidence obtained and only obtainable by a criminal act.' In the same case, Mr. Justice Brandeis, likewise dissenting, said at 479: 'Experience should teach us to be most on our guard to protect liberty when the Government's purposes are beneficent. . . . The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.' And, at 485, Mr. Justice Brandeis added: 'Decency, security and liberty alike demand that government officials shall be subjected to the same rules of conduct that are commands to the citizen. In a government of laws, existence of the government will be imperiled if it fails to observe the law scrupulously. Our Government is the potent, the omnipresent teacher. For good or for ill, it teaches the whole people by its example. Crime is contagious. If the Government becomes a lawbreaker, it breeds contempt for law; it invites every man to become a law unto himself; it invites anarchy.' This principle, thus announced in dissenting opinions, has since been recognized by the Supreme Court as presently the law of the land. *Elkins v. United States*, 364 U.S. 206, 223, 4 L. Ed. 2d 1669, 80 S. Ct. 1437 (1960).

*Knoll Assocs.*, 397 F.2d at 536-537.

116. During the relevant time (2008-2010), Ga. Code Ann. § 16-9-92(11) provided that "Without authority includes the use of a computer or computer network in a manner that exceeds any right or permission granted by the owner of the computer or computer network."

117. Ga. Code. Ann. § 16-9-93(a) provided that any person who uses a computer or computer network with knowledge that such use is without authority and with the intention of "(1) Taking or appropriating any property of another, whether or not with the intention of depriving the owner of possession; (2) Obtaining property by any deceitful means or artful practice; or (3) Converting property to such person's use in violation of an agreement or other known legal obligation to make a specified application or disposition of such property" shall be "guilty of the crime of computer theft."

118. Ga. Code. Ann. § 16-9-93(b) provided “Any person who uses a computer or computer network with knowledge that such use is without authority” and with the intention of “any way removing, either temporarily or permanently any” data shall be “guilty of the crime of computer trespass.”

119. Ga. Code. Ann. § 16-9-93(c) provided “Any person who uses a computer or computer network with the intention of examining any . . . medical . . . or personal data relating to any other person with knowledge that such examination is without authority shall be guilty of the crime of computer invasion of privacy.”

120. Ga. Code. Ann. § 16-9-93(h) provided “Any person convicted of the crime of computer theft, computer trespass, computer invasion of privacy, or computer forgery shall be fined not more than \$50,000.00 or imprisoned not more than 15 years, or both.”

121. During the relevant time (2008-2010), 18 U.S.C. § 1030 prohibited unauthorized computer access to commit fraud and 18 U.S.C. § 1343 prohibited wire fraud.

122. During the relevant time (2008-2010), 42 U.S.C. § 1320d-5 provided “A person who knowingly and in violation of this part . . . obtains individually identifiable health information relating to an individual; or . . . discloses individually identifiable health information to another person, shall be punished” with fines and imprisonment, including \$100,000 and 5 years imprisonment for “false pretenses” conduct and, if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, a fine of not more than \$250,000, and imprisonment of not more than 10 years, or both.

123. Tiversa unlawfully obtained the 1718 File. *See* 18 U.S.C. § 1030; 18 U.S.C. § 1343; 42 U.S.C. § 1320d-6; Ga. Code Ann. §§ 16-9-93 (2008).

124. Johnson and Dartmouth unlawfully obtained the 1718 File in violation of 42 U.S.C. § 1320d-6 because they did not have permission to do so from any consumer or patient listed therein.

125. Tiversa unlawfully disclosed the 1718 File to the Privacy Institute. 42 U.S.C. § 1320d-6.

126. Allowing Complaint Counsel to use *any* of the evidence it obtained in this case violates LabMD's due process rights as a matter of law because *all* of its evidence is directly derived from unlawful conduct by Tiversa and FTC with respect to the 1718 File. *See Knoll Assocs.*, 397 F.2d at 536-537; *Interstate Commerce Com. v. Baird*, 194 U.S. 25, 45 (1902) (noting that the Fourth and Fifth Amendments "run almost into each other").

127. Tiversa is FTC's "agent" as a matter of law. *See United States v. Johnson*, 196 F. Supp. 2d 795, 863 (N.D. Iowa 2002) ("[I]mplicit prearrangement between the government and an informant to gather information in return for a benefit establishes the informant's agency."); *Blum v. Yaretsky*, 457 U.S. 991 (1982). Therefore, the Fourth Amendment applies here.

128. Due process also is offended as a matter of law because the record shows Tiversa disclosed to Complaint Counsel in 2009 that the true origin of the 1718 File was LabMD in Atlanta, Georgia, and so Complaint Counsel and FTC knew or should have known that CX 0019 and Boback's testimony in support thereof, were false and perjured. Nevertheless, Complaint Counsel's expert witnesses rendered reports and gave testimony based on the false evidence and perjured testimony.

129. Due process is also offended as a matter of law because FTC abdicated its duty to investigate or corroborate Tiversa's conduct or allegations. *In re Big Ridge, Inc.*, 36 FMSHRC 1677, 1739 (FMSHRC June 19, 2014) (Mine Safety and Health Review Commission excluded



tainted evidence and found otherwise insufficient evidence to show violation of law); *United States v. Brown*, 500 F.3d 48, 56 (1st Cir. 2007) (authorities must “act with due diligence to reduce the risk of a mendacious or misguided informant”).

130. As a matter of law, FTC had a heightened duty to employ its Consumer Guard and Internet Lab and to take other reasonable measures to ensure Tiversa’s claims were accurate and that Tiversa had not itself violated 42 U.S.C. § 1320d-6 before taking action against Respondent. *See Brown*, 500 F.3d at 56 (authorities must “act with due diligence to reduce the risk of a mendacious or misguided informant”); *United States v. Winchenbach*, 197 F.3d 548, 556 (1st Cir. 1999); *see also Wong Sun v. United States*, 371 U.S. 471, 485 (1963) (in order to use evidence that has been acquired in a prohibited way, the government must have independent source for unlawfully obtained evidence).

131. However, FTC failed to exercise even reasonable due diligence, much less enforce its own subpoena, instead waiting until the close of its case-in-chief to seek leave to investigate the 1718 File’s origins and verify Tiversa’s and Boback’s claims. *See Compl. Counsel Mot. for Leave to Issue Subpoenas for Rebuttal Evidence* at 4 (requesting information regarding “*how, when and where Tiversa found the 1718 File on P2P networks*”) (emphasis added). As a matter of law, this violated Respondent’s due process rights.

132. Any evidence obtained illegally or improperly in the course of FTC’s investigation, and the fruits thereof, should be excluded from the record. *Atlantic Richfield Co.*, 546 F.2d at 651; *FTC v. Page*, 378 F. Supp. 1052, 1056 (N.D. Ga. 1974) (recognizing deterrence of governmental lawlessness would be served by application of the exclusionary rule regardless of the criminal or administrative nature of the proceedings involved, and regardless of the personal or corporate nature of the party aggrieved by the unlawful seizure).

133. Due process is offended as a matter of law by Complaint Counsel's reliance on the civil investigative deposition of Curt Kaloustian. District of Columbia Rule of Professional Conduct 4.2; *United States ex rel. Mueller v. Eckerd Corp.*, 35 F. Supp. 2d 896 (M.D. Fla. 1999); *Camden v. State of Maryland*, 910 F. Supp. 1115 (D. Md. 1996) (prohibiting *ex parte* contact with the former employee of a organizational party when the lawyer knows that the former employee was extensively exposed to privileged information); *see also* FTC Operating Manual § 3.3.6.3 (“[I]t is customary to contact counsel prior to dealing with employees [of represented parties].”), available at [https://www.ftc.gov/sites/default/files/attachments/ftc-administrative-staff-manuals/ch03investigations\\_0.pdf](https://www.ftc.gov/sites/default/files/attachments/ftc-administrative-staff-manuals/ch03investigations_0.pdf). Therefore, as a matter of law Complaint Counsel may not rely on his testimony or on any evidence derivative thereof, including the relevant opinions of Dr. Hill's expert opinion.

134. Due process is also offended as a matter of law by FTC's reliance on Boback's testimony in this case. *See Morris v. Ylist*, 447 F.3d 735, 744 (9th Cir. 2006) (suspected perjury requires an investigation and this “duty to act is not discharged by attempting to finesse the problem by pressing ahead without a diligent and good faith attempt to resolve it”). FTC knew Boback lied no later than May 29, 2014, when Complaint Counsel acknowledged that Boback had misled FTC, and likely when it received CX 0019 in advance of Boback's November, 2013 deposition, and possibly before. It was obligated to take appropriate steps to protect the integrity of this proceeding. *See United States v. Basurto*, 497 F.2d 781, 785 (9th Cir. 1974) (holding that a prosecutor was obligated to inform the court and the grand jury when he became aware of perjured testimony).

135. As matter of law, FTC's reliance on Tiversa to commence its inquisition, and its defense of Tiversa notwithstanding Boback's evident perjury, is precisely the kind of

prosecutorial misconduct that violates LabMD's constitutional rights. *See Mesarosh v. United States*, 352 U.S. 1, 9 (1956) (holding that "it was not within the realm of reason" to require a district court judge to find truthful portions of perjured testimony); *United States v. Basurto*, 497 F.2d 781, 784 (9th Cir. 1974) (prosecutors failure to alert grand jury to perjured testimony violated the defendants constitutional rights); *see also Napue v. Illinois*, 360 U.S. 264, 269 (1959) (prosecutors use of false testimony to secure conviction violated the defendant's constitutional rights).

136. As a matter of law, FTC has, at a minimum, the duty to strip Boback's tainted testimony and all derivative evidence (including expert opinions) from the administrative record. *Subversive Activities Control Bd.*, 351 U.S. at 125 (agency must base findings on untainted evidence and must expunge perjured testimony from the record).

137. Courts expect that federal lawyers with prosecutorial powers will treat targets of government investigations fairly by providing a "more candid picture of the facts and the legal principles governing the case." *See, e.g., James E. Moliterno, The Federal Government Lawyer's Duty to Breach Confidentiality*, 14 Temp. Pol. & Civ. Rts. L. Rev. 633, 639 (2006).

138. As a matter of law, first FTC and later Complaint Counsel were obligated to conduct a detailed and diligent investigation of Tiversa and the 1718 File before proceeding against LabMD. *See* 16 C.F.R. § 2.4 (stating that FTC's investigational policy mandates the "just . . . resolution of investigations").

139. "A government lawyer 'is the representative not of an ordinary party to a controversy,' the Supreme Court said long ago in a statement chiseled on the walls of the Justice Department, 'but of a sovereignty whose obligation . . . is not that it shall win a case, but that justice shall be done.'" *Freeport-McMoran Oil & Gas Co. v. FERC*, 962 F.2d 45, 47-48 (D.C.

Cir. 1992) (quoting *Berger v. United States*, 295 U.S. 78, 88 (1935)). Accordingly, “a government lawyer has obligations that might sometimes trump the desire to pound an opponent into submission.” *Id.* at 48.

C. Due Process: Notice

140. FTC owed LabMD adequate *ex ante* notice of the medical data security practices that it purports to forbid or require. *See Satellite Broad. Co.*, 824 F.2d at 3 (traditional concepts of due process incorporated into administrative law preclude agencies from penalizing private parties for violating rules without first providing adequate notice of their substance); *see also City of Chicago v. Morales*, 527 U.S. 41, 63-64 (1999) (boundless enforcement discretion violates due process); *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926) (statute that either forbids or requires the doing of an act in terms so vague that persons of common intelligence must necessarily guess at its meaning and differ as to its application violates due process); *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002). *Util. Solid Waste Activities Grp.*, 236 F.3d at 754; *Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 632 (D.C. Cir. 2000);

141. Due process is offended if FTC regulates without providing “a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.” *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012).

142. As a matter of law, the testimony of Daniel Kaufman, taken after the MTD Order was issued, demonstrates that FTC lacked constitutionally sufficient standards for LabMD to determine during the relevant time whether its PHI data security practices, which complied with HIPAA, also complied with Section 5(n).

143. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD had actual notice of the Commission's position that Section 5 required something more or different than HIPAA, or, based on the practices of the medical industry during the relevant time, any reason to look for them. *See Diebold*, 585 F.2d at 1333.

144. *S&H Riggers* ruled that "the difficulty with the Commission's approach lies more in its application than its formulation. Without articulating in this or any other case the circumstances in which industry practice is not controlling or the reasons it is not controlling in any particular case, the Commission would decide ad hoc what would be reasonable conduct for persons of particular expertise and experience without reference to the actual conduct which that experience has engendered. In other words, the Commission would assert the authority to decide what a reasonable prudent employer would do under particular circumstances, even though in an industry of multiple employers, not one of them would have followed that course of action." *See* 659 F.2d at 1280-81(internal citations omitted). Therefore, as a matter of law Complaint Counsel bears the burden of proving that LabMD did not adhere to data security practices customary in the medical industry at the time of the alleged violations. *See id.*

145. The Commission acknowledged in its May 19, 2014 Order Denying Respondent LabMD, Inc.'s Motion for Summary Decision that in that order, as in the MTD Order, it ruled only on LabMD's facial fair-notice Due Process challenge and did not address "the extent LabMD is contending that Complaint Counsel, in the course of this adjudication, has yet to identify with specificity what data security standards it alleges LabMD violated" because at that time "the adjudication [was] still underway," nor did it address "other ways to interpret LabMD's statement that might implicate unresolved legal questions or material issues of fact."

See Order Denying Respondent LabMD, Inc.'s Motion for Summary Decision at 7 n.12, *In the Matter of LabMD*, Dkt. No. 9357 (May 19, 2014).

146. FTC lacks jurisdiction under Section 5 to bring a data security case against LabMD, and violated the Constitution's guarantee of due process by bringing this case. See generally LabMD, Inc.'s Motion to Dismiss, *In the Matter of LabMD*, Dkt. No. 9357 (May 27, 2014); LabMD, Inc.'s Motion to Dismiss, *In the Matter of LabMD*, Dkt. No. 9357 (Nov. 12, 2013); LabMD, Inc.'s Motion for Summary Decision, *In the Matter of LabMD*, Dkt. No. 9357 (Apr. 21, 2014); LabMD, Inc.'s Motion to Dismiss, *In the Matter of LabMD*, Dkt. No. 9357 (Apr. 24, 2015). To the extent applicable, the Commission's January 15, 2014 Order Denying Respondent LabMD, Inc.'s Motion to Dismiss and its May 19, 2014 Order Denying LabMD, Inc.'s Motion for Summary Decision are erroneous, but law of the case. LabMD believes that a federal court will find as much, for the reasons briefed and on the basis of additional authority including: *United States v. Chrysler Corp.*, 158 F.3d 1350, 1354-55 (D.C. Cir. 1998), *In re Bogese*, 303 F.3d 1362, 1368 (Fed. Cir. 2002), and *PMD Produce Brokerage v. USDA*, 234 F.3d 48, 51-52 (D.C. Cir. 2000).

147. The Commission acknowledged in its May 19, 2014 Order Denying Respondent LabMD, Inc.'s Motion for Summary Decision that, as in the MTD Order, it ruled only on LabMD's facial fair-notice Due Process challenge and did not address "the extent LabMD is contending that Complaint Counsel, in the course of this adjudication, has yet to identify with specificity what data security standards it alleges LabMD violated" because at that time "the adjudication [was] still underway," nor did it address "other ways to interpret LabMD's statement that might implicate unresolved legal questions or material issues of fact." See Order

Denying Respondent LabMD, Inc.'s Motion for Summary Decision at 7 n.12, *In the Matter of LabMD*, Dkt. No. 9357 (May 19, 2014).

148. Due Process, as applied to LabMD, requires Complaint Counsel to prove that LabMD's PHI data security practices in any given year fell below those that were customary in that same year for a healthcare provider in the medical industry, not an IT company, of LabMD's size and nature. *See S&H Riggers*, 659 F.2d at 1285; *see also Fla. Mach. & Foundry, Inc. v. OSHRC*, 693 F.2d 119, 120 (11th Cir. 1982) (“[A] standard of this generality requires only those protective measures which the employers’ industry would deem appropriate. . . .”) (emphasis added); *B&B Insulation v. OSHRC*, 583 F.2d 1364, 1370 (5th Cir. 1978) (industry-specific standard, *e.g.*, what is customary for sausage industry or roofing industry).

149. A party proffering expert opinion evidence bears the burden of proving its admissibility. *See Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000).

150. The Court must act as a gatekeeper, admitting only that expert testimony which is relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

151. For an expert opinion to be relevant “there must be a ‘fit’ between the inquiry in the case and the testimony.” *United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993).

152. For an expert opinion to be reliable, *Daubert* requires the trier of fact to evaluate: (1) whether the analytic technique or opinion has been subjected to peer review or publication, (2) the “known or potential rate of error,” (3) a “reliability assessment,” in which the “degree of acceptance” within a scientific community may be determined and reviewed, and (4) the “testability” of the opinion. *Daubert*, 509 U.S. at 592-94.

153. An expert must utilize in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

154. An expert witness may testify to industry standards and the breach thereof but not to ultimate legal conclusions. *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008) (excluding expert testimony labeling conduct as “wrongful” or “intentional,” but allowing testimony on “industry standards” and “factual corporate norms”).

155. Dr. Hill did not consider FTC standards and guidelines in rendering her opinion. This fact that was not before the Commission when it issued the MTD Order. Dr. Hill’s inability to discern applicable FTC standards is sufficient to find the Commission has denied LabMD fair notice as a matter of law. *Fabi Constr. Co.*, 508 F.3d at 1084. If Complaint Counsel’s standards expert cannot find competent standards at FTC, then it would be unfair as a matter of law to presume LabMD, which relied on IT professionals experienced in the medical business in developing and operating its data security, to have been able to do so prior to this action. *See L.R. Willson & Sons, Inc. v. Occupational Safety & Health Rev. Comm’n*, 698 F.2d 507, 513 (D.C. Cir. 1983).

D. Due Process: Fair Commission Treatment

156. FTC owes LabMD a constitutional duty of impartiality free from the taint of bias, prejudice, or pre-decision. FTC’s misconduct and indiscretions, from case inception through the OGR investigation of Tiversa, and the statistical certainty that it will find a Section 5 violation *regardless of this Court’s factual and legal findings*, breach this duty as a matter of law. *Withrow*, 421 U.S. at 47.



157. The Commission violated LabMD’s due process rights as a matter of law because FTC’s Rules of Practice render pre-trial motion practice futile. *See* Rules of Practice, 74 Fed. Reg. 20,205 (May 1, 2009); *see also Withrow*, 421 U.S. at 47.

158. Also, the Commission has violated LabMD’s due process rights as a matter of law because it is a statistical certainty that the Commission will find LabMD’s data security practices are unfair under Section 5(n) no matter what this Court does. Nichole Durkin, *Rates of Dismissal in FTC Competition Cases from 1950–2011 and Integration of Decision Functions*, 81 Geo. Wash. L. Rev. 1684 (2013); *see also* Commissioner Joshua Wright, *Recalibrating Section 5: A Response to the CPI Symposium*, CPI Antitrust Chronicle (Nov. 2013) (in “100 percent of cases where the ALJ ruled in favor of the FTC, the Commission affirmed; and in 100 percent of the cases in which the ALJ ruled against the FTC, the Commission reversed”). The government may not lawfully require a party to undergo the burdens of futile litigation. *Cont’l Can Co. v. Marshall*, 603 F.2d 590, 597 (7th Cir. 1979); *accord Withrow*, 421 U.S. at 47.

159. Also, the Commission has violated due process as a matter of law by the appearance of prejudgment. *See In re Dean Foods Co.*, No. 8674, 1966 FTC LEXIS 32, \*332-\*335 (F.T.C. 1966) (fair hearing denied where a disinterested observer would have reason to believe that the Commission had in some measure adjudged the facts of a particular case in advance of hearing it); *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980) (“This requirement of neutrality in adjudicative proceedings safeguards the two central concerns of procedural due process, the prevention of unjustified or mistaken deprivations and the promotion of participation and dialogue by affected individuals in the decisionmaking process. The neutrality requirement helps to guarantee that life, liberty, or property will not be taken on the basis of an erroneous or distorted conception of the facts or the law. At the same time, it preserves both the appearance

and reality of fairness, ‘generating the feeling, so important to a popular government, that justice has been done,’ by ensuring that no person will be deprived of his interests in the absence of a proceeding in which he may present his case with assurance that the arbiter is not predisposed to find against him.”) (citations omitted); *Gibson*, 411 U.S. at 578-79; *In re Murchison*, 349 U.S. 133 136 (1953).

160. There are two ways in which a plaintiff may establish that he has been denied his constitutional right to a fair hearing before an impartial tribunal. First, the proceedings and surrounding circumstances may demonstrate actual bias on the part of the adjudicator. See *Taylor v. Hayes*, 418 U.S. 488, 501-04 (1974); *Cinderella Career and Finishing Schools, Inc. v. FTC*, 425 F.2d 583, 591 (D.C. Cir. 1970). Second, the adjudicator’s personal interest in the outcome of the proceedings may create an appearance of partiality that violates due process, even without any showing of actual bias. *Gibson*, 411 U.S. at 578; see also *Exxon Corp. v. Heinze*, 32 F.3d 1399, 1403 (9th Cir. 1994) (“[T]he Constitution is concerned not only with actual bias but also with ‘the appearance of justice.’”) (citation omitted).

161. The surrounding circumstances establish the Commission’s bias as a matter of law because the Commission wrongfully used its enforcement authorities to retaliate against LabMD for speaking out against government overreach. See *Trudeau v. FTC*, 456 F.3d 178, 190-91, 190 n.22 (D.C. Cir. 2006) (official reprisal for constitutionally-protected speech violates the First Amendment); see also *White v. Baker*, 696 F. Supp. 2d 1289, 1312-13 (N.D. Ga. 2010).

162. The circumstances suggest an appearance of partiality by the Commission against LabMD as a matter of law. The OGR investigation creates powerful institutional incentives for the Commission to prejudge this matter, because only a judgment against LabMD will rescue the Commission’s reputation – any other result confirms government misconduct and creates

potential civil liability. *Pillsbury Co.*, 354 F.2d at 964 (litigant’s right to a fair trial is breached where agency officials in judicial function are subjected to powerful external influences).

163. Furthermore, the Commission has refused to comply with APA provisions governing *ex parte* contacts between it and Congress regarding matters relating to the facts and circumstances of this case. *See* 5 U.S.C. § 557(d)(1)(A); *Aera Energy LLC*, 642 F.3d at 220-22; *see also United Steelworkers of Am.*, 647 F.2d at 1213 (D.C. Cir. 1980) (APA prohibits off-the-record communication between agency decision maker and any other person about a fact in issue); *Pillsbury Co.*, 354 F.2d at 964. The only cure for such *ex parte* contact is full disclosure by Complaint Counsel of all *ex parte* communications and documents exchanged with Congress, which the Commission has refused to do. 5 U.S.C. § 557(d)(1)(A); *Aera Energy LLC*, 642 F.3d at 220-22. The Commission’s refusal to disclose, when viewed in context of all the other facts and circumstances of this case, taints the proceeding with the appearance of bias as a matter of law.

#### VIII. COMPLAINT COUNSEL’S EXPERT DEFICIENCIES

164. Complaint Counsel introduced testimony from three expert witnesses and one rebuttal expert to prove its case. When ruling on expert opinions, “courts consider whether the expert is qualified in the relevant field and examine the methodology the expert used in reaching the conclusions at issue.” *In re McWane, Inc.*, 2012 FTC LEXIS 142, at \*8 (F.T.C. Aug. 16, 2012) (citations omitted).

165. *Daubert* mandates a “rigorous three-part inquiry” assessing: (1) the expert’s qualifications; (2) the reliability of the expert’s methodology; and (3) whether the expert’s testimony assists the factfinder, “through the application of scientific, technical, or specialized expertise. . . .” *Daubert*, 509 U.S. 579; *see Hendrix v. Evenflo*, 609 F.3d 1183, 1194 (11th Cir.

2010); *AG of Okla. v. Tyson Foods, Inc.*, 565 F.3d 769, 780 (10th Cir. 2009). Complaint Counsel bears the burden of showing by preponderant evidence that an expert's proposed testimony independently satisfies all three prongs. *See id.*; *see generally Amorgianos v. Amtrak*, 303 F.3d 256, 267 (2d Cir. 2002) ("expert's analysis [must] be reliable at every step").

166. A witness who invokes 'my expertise' rather than analytic strategies widely used by specialists is not an expert as Rule 702 defines that term." *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005).

167. Nothing requires a court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. *See Gen. Electric v. Joiner*, 522 U.S. 136, 146 (1997).

168. An expert's bald assurance of validity is not enough to show reliability. Rather, the party presenting the expert must show that the expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology. *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Testimony based on insufficient or incorrect facts is not reliable. *See Allen v. LTV Steel Co.*, 68 Fed. Appx. 718, 721-22 (7th Cir. 2003); *Guillory v. Domtar Indus.*, 95 F.3d 1320, 1330-1331 (5th Cir. 1996).

169. For example, in a case where the expert witness formed an opinion that coal dust caused the plaintiffs' symptoms based on the experts' knowledge about coal dust exposure generally plus the plaintiffs' subjective beliefs that they had been exposed to coal dust, not a scientific determination that they had been exposed, his "opinion was not based upon 'sufficient facts or data,'" and therefore was properly excluded. *Korte v. ExxonMobil Coal USA, Inc.*, 164 Fed. Appx. 553, 557 (7th Cir. 2006); *cf. Nunez v. BNSF Ry. Co.*, 730 F.3d 681, 684 (7th Cir. 2013).

170. An expert’s testimony must “fit” the case at hand. For example, the testimony of a chemistry expert that a ladder had a manufacturing defect because of a lack of adhesion between its chemical components did not fit the facts of the case because the legal standard for a manufacturing defect was whether the product deviated in a material way from the industry’s manufacturing specifications, and the expert did not assess whether the ladder met those standards. *See Leverette v. Louisville Ladder Co.*, 183 F.3d 339, 341 (5th Cir. 1999).

171. An expert’s opinion is presumed unreliable when driven by a financial incentive. *Lust by & Through Lust v. Merrell Dow Pharms.*, 89 F.3d 594, 597-98 (9th Cir. 1996); *see also Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1359 (N.D. Ga. 1999).

A. Dr. Hill

172. Dr. Hill’s opinion does not “fit” this case as a matter of law for she evaluated LabMD’s data security using broad, general IT principles from 2014 and without reference to or apparent knowledge of medical industry standards and practices during the relevant time.

173. She considered only the HIPAA security rule but did not consider the rest of the statutory or regulatory HIPAA/HITECH data security regime or perform the “scalability” analysis HIPAA requires to differentiate between large and small medical providers. However, “scalability” is a key tenet of HIPAA’s security standard, providing that data security compliance must be judged according to the size and nature of the medical provider in question. *See Health Insurance Reform: Security Standards*, 68 Fed. Reg. 8334, 8338-49, 8351, 8359-64, 8367-69, 8372-73 (Feb. 20, 2003); *see also* 45 C.F.R. Parts 160, 162, 164.

174. Also, Dr. Hill testified that LabMD should have designed its IT system differently. In cases where experts have testified that a product should have employed an alternative design, even where the alternative designs “involve only simple components and

widely-accepted engineering principle[s],” the alternative design must have been tested and found appropriate. *Cummins v. Lyle Indus.*, 93 F.3d 362, 368 (7th Cir. 1996). Otherwise, the expert is offering only “unverified statements,” “unsupported by any scientific method,” constituting a “type of unsubstantiated testimony.” *See id.* at 368-69. Dr. Hill, in rendering her opinion, proposed an ideal hypothetical data security system, an untested alternative design LabMD should have implemented.

175. Dr. Hill opined LabMD’s data security was “unreasonable” and made “recommendations.” However, Dr. Hill could not opine whether LabMD’s data security is “unreasonable” because this is the ultimately legal issue. *Nationwide Transp. Fin.*, 523 F.3d at 1058.

B. Clay Shields

176. As a rebuttal expert, Shields’ opinion is necessarily limited to rebuttal of Fisk’s testimony. *See* FTC Rule § 3.31A(a).

C. Jim Van Dyke

177. Complaint Counsel asked Van Dyke to serve as an expert witness in this case in early 2013. The Javelin survey that Van Dyke conducts, and which he relied on in this case, contains new questions in each year. In October of 2013, Van Dyke conducted the survey that he would use as the basis for his opinion in this case. (Van Dyke, Tr. 636-637). Van Dyke had been retained by Complaint Counsel for the better part of a year before conducting the survey on which he testified. Here, as in *Lust*, it is reasonable to presume Van Dyke’s testimony is colored by a litigation-driven financial incentive. As a result, its weight is substantially diminished as a matter of law.

178. Van Dyke's statistical analysis fails *Daubert* as a matter of law. First, the Javelin survey was conducted via the internet without any reliable means of confirming that identities of those who receive the survey match those of the subjects the survey intends to target, giving rise to the likelihood of serious sampling error. Second, he projected an anticipated fraud impact to consumers due to unauthorized disclosure of the 1718 File and the Day Sheets of between 7.1% and 13.1%. However, Van Dyke's claims were belied by empirical data: The actual fraud impact to consumers in this case proven by Complaint Counsel is 0%. This suggests the Javelin survey is methodologically flawed and that its results are inherently unreliable. *EEOC v. Freeman*, 778 F.3d 463, 466, 469 (4th Cir. 2015) (citations omitted).

D. Rick Kam

179. As a matter of law, Kam's testimony is not reliable because his methods have neither been verified by testing nor peer reviewed nor evaluated for potential rate of error. *Kumho Tire Co.*, 526 U.S. at 157; *Freeman*, 778 F.3d at 469 (citing cases); *Allen v. LTV Steel Co.*, 68 Fed. Appx. at 721-22.

180. Kam is not qualified to give the expert opinion he provided. As a matter of law, his testimony should not be relied upon. *Elcock v. Kmart Corp.*, 233 F.3d 734 (3rd Cir. 2000) (trial court erred in not holding a *Daubert* hearing, where damages expert relied on dubious methodology, and expert's qualifications were minimal: where qualifications are a "close call," this factor weighs in favor of excluding the testimony as unreliable).

181. Kam's opinion is undermined by his financial entanglements. *See Lust by & Through Lust*, 89 F.3d at 597-98.

182. Kam's analysis does not "fit" the facts of the case as a matter of law because an expert witness's opinion that one thing caused another must identify and rule out other likely

causes. *People Who Care v. Rockford Bd. of Educ.*, 111 F.3d 528, 537-38 (7th Cir. 1997); *Sorensen by & Through Dunbar v. Shaklee Corp*, 31 F.3d 638, 649 (8th Cir. 1994).

183. Surveys in particular are unreliable where, as here, they contain systematic errors such as nonresponse or sampling bias. *See Freeman*, 778 F.3d at 466, 469; *In re Countrywide Fin. Corp. Mortgage-Backed Secs. Litig. v. Countrywide Fin. Corp.*, 984 F. Supp. 2d 1021, 1038 (C.D. Cal. 2013).

184. When an expert relies on uncorroborated assumptions for a factual premise for his opinion, the opinion is unreliable as a matter of law. *See Korte*, 164 Fed. Appx. at 557; *Casey v. Geek Squad*, 823 F. Supp. 2d 334, 340-41 (D. Md. 2011); *cf. Nunez v. BNSF Ry. Co.*, 730 F.3d 681, 684 (7th Cir. 2013); *Guillory v. Domtar Indus.*, 95 F.3d 1320, 1330-31 (5th Cir. 1996) (“Expert evidence based on a fictitious set of facts is just as unreliable as evidence based upon no research at all. Both analyses result in pure speculation.”). Kam uncritically relied on Boback and Tiversa, so his opinion is unreliable as a matter of law. *Guillory*, 95 F.3d at 1330-31.

185. Because Kam’s entire analysis of the likelihood of harm from the Day Sheets was premised on the CLEAR database, which was excluded from this case, his opinion lacks a reliable factual basis as a matter of law and must be excluded. *Geek Squad*, 823 F. Supp. 2d at 340-44.

186. Kam’s opinion falsely assumed that the suspects in whose Sacramento house LabMD’s Day Sheets were found had “identity theft charges and convictions prior to the events in Sacramento on October 5, 2012,” when in fact they did not. Therefore, Kam’s opinion regarding consumer harm from the Day Sheets is unreliable and irrelevant as a matter of law. *See Korte*, 164 Fed. Appx. at 557.



187. Kam conducted essentially no analysis of the risk of harm to consumers from LabMD's general security measures. As a matter of law, an expert may not simply accept another expert's opinion: "[e]xperts may not . . . simply repeat or adopt the findings of [others] without investigating them." *See Hendrix v. Evenflo Co., Inc.*, 255 F.R.D. 568, 607 (N.D. Fla. 2009), *aff'd* at 609 F. 3d 1183 (11th Cir. 2010).

188. Testimony cannot be conclusory. *See Roberts v. Menard, Inc.*, No.4:09-cv-59-PRC, 2011 U.S. Dist. LEXIS 44628, at \*11-\*17. (N.D. Ind. Apr. 25, 2011). Experts cannot simply mention that something is possible; they must quantify its likelihood for their opinion to be relevant and reliable. When "experts testify to a possibility rather than a probability" and do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted, even though the substantive legal standard has always required proof of causation by a preponderance of the evidence, this renders their testimony inadmissible. *See Daubert*, 43 F.3d at 1322.

189. Emotional harm such as embarrassment or reputational impact does not constitute "substantial injury" under Section 5. *See* Fed. Trade Comm'n, *FTC Policy Statement on Unfairness*, <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness> (last visited August 9, 2015).

#### IX. COMPLAINT COUNSEL HAS FAILED TO PROVE UNREASONABLENESS

190. As a matter of law, Complaint Counsel has not proven by a preponderance of the evidence that LabMD's data security acts or practices between 2005 and 2010 cause, or are likely to reoccur and then to cause substantial consumer injury, which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. *See* 15 U.S.C. § 45(n).

191. Complaint Counsel must affirmatively prove by preponderant evidence that LabMD's data security practices were "unreasonable." MTD Order at 18-19. This standard cannot be construed in a way that violates LabMD's due process rights.

192. As a matter of law, the Commission has not previously promulgated by rulemaking or adjudication a "reasonableness" standard applicable to Respondent or the medical industry.

193. As a matter of law due process requires the Commission to articulate and apply an *objective* and *industry-specific* "reasonableness" standard of care to Respondent before commencing action against it. 5 U.S.C. § 552(a)(1)(D); *see Fla. Mach. & Foundry*, 693 F.2d at 120 ("[A] standard of this generality requires only those protective measures which the employers' industry would deem appropriate....") (emphasis added); *S&H Riggers*, 659 F.2d at 1285; *B&B Insulation*, 583 F.2d at 1370 (industry-specific standard, *e.g.*, what is customary for sausage industry or roofing industry).

194. As a matter of law, Complaint Counsel must prove Respondent failed to comply with the medical industry standards in effect during the time 2005 – 2010.

195. As a matter of law, Complaint Counsel has not proven the objective, medical-industry "reasonableness" standard of care in effect between 2005 – 2010 that LabMD should have followed for PHI data security, nor proven by preponderant evidence that LabMD violated it.

196. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD's data security acts or practices were "unfair" as that word is commonly defined, *e.g.*, dishonest, contrary to law, or unethical.

197. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD's current data security acts or practices cause or are likely to cause consumers substantial injury in the future.

198. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD's 2005-2010 data security acts or practices are "likely" (probable) either to reoccur or, if they were somehow to do so, to cause consumers substantial injury.

199. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence current or likely substantial consumer injury in the future.

200. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD unreasonably relied on its data security specialists.

201. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that the data security program described by Dr. Hill was actually used by any medical provider during the relevant time or today.

202. As a matter of law, Tiversa and FTC colluded in the transfer of the 1718 File from Tiversa to the Privacy Institute in violation of HIPAA, 42 U.S.C. § 1320d-5.

203. As a matter of law, Tiversa functioned as FTC's agent because enforcement action against LabMD and other companies similarly-situated was viewed as mutually beneficial. *See Johnson*, 196 F. Supp. 2d at 863.

204. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD's data security practices between 2005 and 2010 caused substantial injury to a single consumer.

205. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD's data security practices between 2005 and 2010 are likely to reoccur

and cause substantial injury to consumers. *See Borg-Warner Corp.*, 746 F.2d at 110. “Merely speculative harms” do *not* constitute “substantial injury” sufficient to support a finding of unfairness under Section 5(n). Fed. Trade Comm’n, *FTC Policy Statement on Unfairness*, <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness> (last visited August 9, 2015).

206. As a matter of law, mere speculation that LabMD’s data security could have put consumers at a potentially increased risk of injury is not “substantial injury” under Section 5(n).

207. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that any benefit in terms of reduced risk from changing LabMD’s data security practices would have outweighed not only the costs to LabMD, but also the additional burdens to the doctors and their patients who benefitted from the potentially life-saving speed and accuracy of LabMD’s system.

208. Complaint Counsel has failed to prove by a preponderance of the evidence the allegation in ¶ 18(b) of the Complaint that in May 2008 “the P2P insurance aging file was one of hundreds of files that were designated for sharing from [LabMD’s] billing computer using Limewire.” There is no evidence LabMD designated the 1718 File for sharing because Woodson was not authorized to bind the corporation and her conduct was contrary to LabMD policy.

209. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence the allegation in ¶ 21 of the Complaint that “[i]n October 2012, the Sacramento, California Police Department found more than 35 Day Sheets and a small number of copied checks in the possession of individuals who pleaded no contest to state charges of identity theft.”

210. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence the allegation in ¶ 21 of the Complaint that “[m]any of these consumers were not

included in the P2P insurance aging file, and some of the information post-dates the P2P insurance aging file.”

211. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence the allegation in ¶ 21 of the Complaint that “[a] number of the SSNs in the Day Sheets are being, or have been, used by people with different names, which may indicate that the SSNs have been used by identity thieves.”

212. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence the allegations in ¶ 22 of the Complaint that any action or practice by LabMD in this case for the period January 1, 2005 to and including July 31, 2010 was “an unfair act or practice” within the meaning of Section 5(n). *See* Hon. Julie Brill, Comm’r, Fed. Trade Comm’n, Responses to Sen. Kelly Ayotte (QFR), U.S. S. Comm. on Commerce, Sci. & Transp.: Privacy and Data Security: Protecting Consumers in the Modern World at 223 (June 19, 2011), *available at* [http://www.governmentattic.org/13docs/FTC-QFR\\_2009-2014.pdf](http://www.governmentattic.org/13docs/FTC-QFR_2009-2014.pdf) (“***The Commission will not bring a case where the evidence shows no actual or likely harm to competition or consumers.*** As the Chairman explained in his testimony before the Senate Judiciary Committee last summer, ‘Of (*sic*) course, ***in using our Section 5 authority the Commission will focus on bringing cases where there is clear harm to the competitive process and to consumers.***’ *That is, any case the Commission brings under the broader authority of Section 5 will be based on demonstrable harm to consumers or competition.*”) (emphasis added).

213. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that the acts and/or practices of LabMD as alleged in the Complaint constitute “clear harm to the competitive process and to consumers” or “demonstrable harm to consumers

or competition” in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). *See* Hon. Julie Brill, Comm’r, Fed. Trade Comm’n, Responses to Sen. Kelly Ayotte (QFR), U.S. S. Comm. on Commerce, Sci. & Transp.: Privacy and Data Security: Protecting Consumers in the Modern World at 223 (June 19, 2011), *available at* [http://www.governmentattic.org/13docs/FTC-QFR\\_2009-2014.pdf](http://www.governmentattic.org/13docs/FTC-QFR_2009-2014.pdf).

214. As a matter of law, Complaint Counsel bears the burden of proving LabMD’s data security was unreasonable. MTD Order at 18-19. However, the evidence is LabMD’s data security was reasonable at all relevant times as a matter of law.

X. INJURY WAS “AVOIDABLE”

215. To prove a Section 5(n) case, Complaint Counsel must show that LabMD’s data security practices were likely to cause substantial injury “which is not reasonably avoidable by consumers themselves.” *See* 15 U.S.C. § 45(n). “Consumers may act to avoid injury before it occurs if they have reason to anticipate the impending harm and the means to avoid it, or they may seek to mitigate the damage afterward if they are aware of potential avenues toward that end.” *Orkin Exterminating Co. v. FTC*, 849 F.2d 1354, 1365 (11th Cir. 1988).

216. As a matter of law, Complaint Counsel has failed to prove any consumers suffered substantial injury as defined under Section 5(n) due to either of the Security Incidents in the Complaint.

217. Established judicial principles suggest “substantial injury” under Section 5(n) must at least be more than an “injury in fact,” that is, the invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Lujan*, 504 U.S. at 560. While the test for constitutional standing is low, *see, e.g., Blunt*, 767 F.3d at 278 (requiring only “some specific, identifiable trifle of injury”), Section 5(n)

contains two additional requirements: the injury must be (1) “substantial,” which, to have any meaning, must be something more than the injury required by Article III; and, (2) not “reasonably avoidable by consumers themselves.” 15 U.S.C. § 45(n).

218. In data breach cases where no misuse is proven there has been no injury as a matter of law. *Reilly*, 664 F.3d at 44.

219. An “injury” is not actionable under Section 5(n) “if consumers are aware of, and are reasonably capable of pursuing, potential avenues toward mitigating the injury after the fact.” *HSBC Bank Nevada*, 691 F.3d at 1168-69. The issue “not whether subsequent mitigation was convenient or costless, but whether it was reasonably possible.” *Id.* at 1169. As a matter of law, speculation about the potential time and money consumers could spend resolving fraudulent charges cannot satisfy Section 5(n), or even confer standing under Article III. *See id.*; *Reilly*, 664 F.3d at 46 (alleged time and money expenditures to monitor financial information do not establish standing, “because costs incurred to watch for a speculative chain of future events based on hypothetical future criminal acts are no more ‘actual’ injuries than alleged ‘increased risk of injury’ claims”); *Randolph*, 486 F. Supp. 2d at 8 (“[L]ost data” cases “clearly reject the theory that a plaintiff is entitled to reimbursement for credit monitoring services or for time and money spent monitoring his or her credit.”). That a plaintiff has willingly incurred costs to protect against an alleged increased risk of identity theft is not enough to demonstrate a “concrete and particularized” or “actual or imminent” injury. *In re Sci. Applications Int’l Corp.*, 45 F. Supp. 3d at 28-33 (listing cases).

220. Even if such injury had occurred, Complaint Counsel has failed as a matter of law to prove by a preponderance of the evidence that such injury was not “reasonably avoidable.” As the Ninth Circuit explained in *Davis v. HSBC Bank* that an “injury” is not actionable under

Section 5(n) “if consumers are aware of, and are reasonably capable of pursuing, potential avenues toward mitigating the injury after the fact.” 691 F.3d at 1168-69. *Davis* rejected the notion that avoiding injury is itself sufficient, framing the issue as “not whether subsequent mitigation was convenient or costless, but whether it was reasonably possible.” *Id.*

XI. COMPLAINT COUNSEL HAS FAILED TO PROVE COUNTERVAILING BENEFIT WAS OUTWEIGHED BY RISK IN THIS CASE

221. As a matter of law, Complaint Counsel has failed to prove by a preponderance of the evidence that LabMD’s data security practices were likely to cause substantial injury “not outweighed by countervailing benefits to consumers.” *See* 15 U.S.C. § 45(n).

222. LabMD’s business model offered groundbreaking benefits to doctors and patients, delivering pathology results to doctors electronically at unprecedented speed, allowing them to more quickly tell anxiously waiting patients whether they had cancer and to begin treatment immediately if needed. However, FTC did not offer a reasoned countervailing benefit analysis as required by law. *Fox Television Stations, Inc.*, 556 U.S. at 515 (noting “the requirement that an agency provide reasoned explanation for its action”).

XII. FTC IS NOT ENTITLED TO THE REQUESTED RELIEF

223. Section 5 does not specifically authorize FTC to issue a notice order with the Complaint. Consequently, the “notice order” is either a judicially reviewable final order and violates due process because it demonstrates this case has been prejudged or it is an *ultra vires* act in violation of the APA.

224. As a matter of law, Complaint Counsel’s proposed order is not equitable but punitive in nature and the Commission is not authorized to issue punitive orders. *Heater v. FTC*, 503 F.2d 321, 322-327 (9th Cir. 1974) (overturning an FTC order for restitution as inconsistent with the purpose of the FTC Act, which does not authorize punitive or retroactive punishment);



MTD Order at 18 (“[F]act-finders in the tort context find that corporate defendants have violated an unwritten rule of conduct, they – unlike the FTC – can normally impose compensatory and even punitive damages.”). The Commission then argued incorrectly that not pursuing criminal or civil penalties for past conduct somehow divests it of the constitutional requirement to provide fair notice. However, even if this argument were not incorrect, *see, e.g., United States v. Chrysler Corp.*, 158 F.3d at 1354-55, *In re Bogese*, 303 F.3d at 1368, and *PMD Produce Brokerage*, 234 F.3d at 51-52, the evidence does not support the claimed relief.

225. There is no basis in law to require LabMD to comply with requirements such as establishing a “comprehensive information security program,” hiring outside professionals to conduct biannual audits, and hiring additional personnel to monitor the security of data that is not being actively used and is being kept on computers that are stored with the power off. *Borg-Warner Corp.*, 746 F.2d at 110-11.

226. As a matter of law, Complaint Counsel has failed to allege or prove by a preponderance of the evidence that LabMD’s past course of conduct provides a legally sufficient basis for believing that it will violate Section 5(n) in the future.

227. As a matter of law, “fencing-in” relief, which extends to future conduct by LabMD, is inappropriate in this case. *See Riordan*, 627 F.3d at 1234.

228. Such relief “must be sufficiently clear that it is comprehensible to the violator, and must be ‘reasonably related’ to a violation of the [FTC] Act.” *See In re Daniel Chapter One*, 2009 FTC LEXIS 157, at \*280-\*281 (citations omitted). Whether fencing-in relief bears a “reasonable relationship” to the conduct found to be unlawful depends on: “(1) the deliberateness and seriousness of the violation; (2) the degree of transferability of the violation to other products; and, (3) any history of prior violations.” *See id.* It must be “reasonably calculated to

prevent future violations of the sort found to have been committed.” See *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 221-22 (2d Cir. 1976).

229. The first factor for fencing-in relief is “the deliberateness and seriousness of the violation.” See *In re Daniel Chapter One*, 2009 FTC LEXIS 157, at \*280-281. As a matter of law, Complaint Counsel has failed to allege or prove by a preponderance of the evidence that LabMD knowingly violated Section 5 or that such violations were “serious.” Compare *In the Matter of Daniel Chapter One*, 2009 FTC LEXIS 157, at \*281-282, with *In the Matter of POM Wonderful LLC*, 2012 FTC LEXIS 18, at \*97-\*98 (F.T.C. Jan. 11, 2012). Complaint Counsel does not dispute that LabMD’s data security complied with HIPAA and has not alleged or proven that a HIPAA-compliant data security program could be a “serious” violation of Section 5.

230. The second factor is “the degree of transferability of the violation to other products.” See *In re Daniel Chapter One*, 2009 FTC LEXIS 157, at \*280-\*281. As a matter of law, Complaint Counsel has failed to allege or prove transferability in this case.

231. The third factor is “history of prior violations.” See *id.* Complaint Counsel has not alleged or proven any.

232. Fencing-in relief is therefore both unnecessary and unlawfully punitive in this case. See *Riordan*, 627 F.3d at 1234 (“[W]e have stated that a cease-and-desist order is ‘purely remedial and preventative’ and not a ‘penalty’ or ‘forfeiture.’”) (citing *Drath v. FTC*, 239 F.2d 452, 454 (D.C. Cir. 1956)). Complaint Counsel seeks an Order requiring LabMD to hire outside contractors to conduct biannual assessments, send letters to all persons on the 1718 File (notwithstanding there is no evidence of breach or injury) and establish a hotline and website, implement onerous document retention requirements, and meet agency reporting requirements

for twenty years. *See* Compl. at 12, *In the Matter of LabMD*, Dkt. No. 9357 (Aug. 28, 2013).

However, as a matter of law it has not proven that such relief is appropriate.

233. Also, Complaint Counsel's demanded relief includes a prohibited "obey-the-law" provision. The Complaint demands an Order requiring LabMD to:

[N]o later than the date of service of this order, establish and implement, and thereafter maintain, a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers by respondent or by any corporation, subsidiary, division, website, or other device or affiliate owned or controlled by respondent. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers, including:

A. The designation of an employee or employees to coordinate and be accountable for the information security program;

B. The identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures;

C. The design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures;

D. The development and use of reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from respondent, and requiring service providers by contract to implement and maintain appropriate safeguards; and

E. The evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by Subpart C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

Compl. at ¶ 7-8. If FTC gave LabMD notice during the relevant time (2005-2010) that Section 5 required these things, as Complaint Counsel has argued, then the proposed order is an invalid "obey-the-law" provision. *SEC v. Goble*, 682 F.3d 934, 949 (11th Cir. 2012). If FTC did not give LabMD notice during the relevant time that Section 5 required these things, then, by definition, LabMD lacked constitutional fair notice. *Fabi Construction Co.*, 508 F.3d at 1088.

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**CERTIFICATE OF SERVICE**

**I hereby certify** that on August 11, 2015, I caused to be filed the foregoing document electronically through the Office of the Secretary's FTC E-filing system, which will send an electronic notification of such filing to the Office of the Secretary:

Donald S. Clark, Esq.  
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**I also certify** that I delivered via hand delivery and electronic mail copies of the foregoing document to:

The Honorable D. Michael Chappell  
Chief Administrative Law Judge  
Federal Trade Commission  
600 Pennsylvania Ave., NW, Rm. H-110  
Washington, DC 20580

**I further certify** that I delivered via electronic mail a copy of the foregoing document to:

Alain Sheer, Esq.  
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**CERTIFICATE OF ELECTRONIC FILING**

**I certify** that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

Dated: August 11, 2015

/s/ Reed D. Rubinstein

Notice of Electronic Service

**I hereby certify that on August 11, 2015, I filed an electronic copy of the foregoing Respondent LabMD, Inc.'s CORRECTED Proposed Conclusions of Law, with:**

D. Michael Chappell  
Chief Administrative Law Judge  
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Donald Clark  
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**I hereby certify that on August 11, 2015, I served via E-Service an electronic copy of the foregoing Respondent LabMD, Inc.'s CORRECTED Proposed Conclusions of Law, upon:**

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