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# FOOD FORENSICS IN CLASS ACTION LITIGATION: THE RACE BETWEEN PLEADING STANDARDS AND TECHNOLOGY

Jeff Lingwall\*

This Article examines the emerging use of “food forensics” to discover injury in class action litigation. Based on increased public interest in what goes inside food, plaintiffs are beginning to rely on statistical and chemical testing to verify label claims. The test results often spur producers to re-examine their products, but can also raise plausibility concerns under the veneer of science and deny consumers data they need to make informed decisions about food. Drawing on examples ranging from olive oil to multivitamins and canned octopus to pet food, I show how product testing in litigation represents a race between the resolving power of test results and slower-moving interpretation of pleading standards. I then propose a framework for navigating testing claims based on traditional case screening tools and statistical principles.

## I. INTRODUCTION

Recent years have brought increasing public sensitivity to what goes inside food, this is reflected by a host of books and documentaries such as *The Omnivore’s Dilemma*, *Real Food/Fake Food*, and *Food, Inc.*<sup>1</sup> Not surprisingly, this movement has been accompanied by litigation, such as disputing the use of “natural” on food labels. While

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1. This is an extensive area of literature. See, e.g., MIKE ADAMS, *FOOD FORENSICS: THE HIDDEN TOXINS LURKING IN YOUR FOOD AND HOW YOU CAN AVOID THEM FOR LIFELONG HEALTH* (2016); LARRY OLMS TED, *REAL FOOD / FAKE FOOD: WHY YOU DON’T KNOW WHAT YOU’RE EATING & WHAT YOU CAN DO ABOUT IT* (2016); ERIC SCHLOSSER, *FAST FOOD NATION: THE DARK SIDE OF THE ALL-AMERICAN MEAL* (2012); *FOOD, INC.* (Participant Media 2008); MICHAEL POLLAN, *THE OMNIVORE’S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* (2006). See also MICHAEL POLLAN, *THE OMNIVORE’S DILEMMA: THE SECRETS BEHIND WHAT YOU EAT* (2015); MICHAEL POLLAN, *IN DEFENSE OF FOOD: AN EATER’S MANIFESTO 1* (2008) (“Eat food. Not too much. Mostly plants.”); MICHAEL POLLAN, *FOOD RULES: AN EATER’S MANUAL* (2009); Irena Dumitrescu, *The Curious Appeal of ‘Bad’ Food*, *THE ATLANTIC*, Aug. 5, 2016, <http://www.theatlantic.com/entertainment/archive/2016/08/the-curious-appeal-of-bad-food/494255/> (“Experts shout culinary commandments from every direction: Daily meals . . . must be ethically sourced, organic, raw, gluten-free, meat-free, dairy-free, protein-rich, low-fat, low in sodium, carbon neutral, dirt-encrusted, pre-soaked, and fair trade. It can be hard to keep track of all these contradictory gastronomic rules.”). Nor have law reviews been spared. E.g., Rebecca L. Goldberg, *Administering Real Food: How the Eat-Food Movement Should—and Should Not—Approach Government Regulation*, 39 *ECOLOGY L.Q.* 773, 815 (2012) (discussing whether the “eat food” movement should pursue increased labeling regulation); James I. Pearce, *A Brave New Jungle: Factory Farming and Advocacy in the Twenty-First Century*, 21 *DUKE ENVTL. L. & POL’Y F.* 433, 451-54 (2010) (describing

this has drawn attention in the academic literature,<sup>2</sup> the use of “food forensics”—its emerging core—has not.<sup>3</sup> This Article fills the gap. Using examples ranging from pet food to olive oil, multivitamins, wine, oats, and canned octopus, it shows that product testing has resulted in a race between the ever-better resolving power of test results and the slower-moving evolution of pleading standards, a race in which increasingly powerful testing methods stretch the boundaries of legal injury.<sup>4</sup> Due to asymmetric litigation costs, producers may react to even implausible legal theories by changing labeling. As a result, the same consumers this litigation intends to protect may find themselves without the data necessary to make informed decisions about food.

For example, while testing provides a path for independent verification of food labeling, testing allegations often assume a life of their own before scientific and legal issues are resolved. For instance, pet food giant, Nestlé Purina, attacked a rival producer of high end pet food, Blue Buffalo (“Blue”), based on the results of “highly sophisticated . . . independent laboratory” testing, that claimed to identify the presence of undisclosed animal byproducts in Blue’s food.<sup>5</sup> Based on this alleged testing, thirteen consumer class action lawsuits, spanning the United States, were filed against Blue, none of which performed additional testing.<sup>6</sup> When Blue sought details on the

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public health concerns from industrial food production); Kate L. Harrison, *Organic Plus: Regulating Beyond the Current Organic Standards*, 25 PACE ENVTL. L. REV. 211, 211-13 (2008) (discussing the organic food movement); Morgan L. Holcomb, *Book Review: Our Agricultural Policy Dilemma: The Omnivore’s Dilemma: A Natural History of Four Meals*, by Michael Pollan, 8 MINN. J. L. SCI. & TECH. 249, 272-75 (2007) (putting the “real food” movement in context of food security).

2. See, e.g., Melissa Mortazavi, *Tort as Democracy: Lessons from the Food Wars*, 57 ARIZ. L. REV. 929, 945-50, 962-65 (2015) (discussing the role of “natural” food litigation in cultural discourse); Sarah Valenzuela, *Tracing the Evolution of Food Fraud Litigation: Adopting an Ascertainability Standard that is “Natural”*, 34 REV. LITIG. 609, 616-34 (2015) (describing trends in food fraud litigation, from preemption challenges to attacks on class ascertainability); Shea Thompson, *Artificially “Natural”: Class Action Lawsuits Attack Misleading “Natural” Claims in FDA’s Absence*, 47 IND. L. REV. 893, 897-907 (2014) (describing “natural” litigation).

3. See *supra* note 2. See also Paul Chan, *Liability Labels: Consumer Groups and Regulators Are Continuing to Test New Theories Against Manufacturers Over Food Labels*, 37 L.A. LAWYER 25, 25-29 (2015) (surveying labeling litigation without discussing product testing); Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. 815, 849-51 (2015) (surveying litigation surrounding the NLEA without discussing product testing litigation); Sylvia Zarski, *Comment: Can You Judge Your Food by Looking at Its Cover? How Courts’ Application of Federal Preemption Allows Misleading Food Labeling to Slip Through the Regulatory Cracks*, 64 DEPAUL L. REV. 1119, 1128-36 (2015) (discussing preemption challenges to food labeling litigation without discussing testing). See generally MIKE ADAMS, FOOD FORENSICS: THE HIDDEN TOXINS LURKING IN YOUR FOOD AND HOW YOU CAN AVOID THEM FOR LIFELONG HEALTH (2016) (testing common food products for presence of contaminants); Rahi Azizi, “*Supplementing the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act*,” 98 CAL. L. REV. 439, 461-66 (2010) (advocating for regulatory pre-market testing of dietary supplements under the NLEA); S. Primrose, M. Woolfe, & S. Rollinson, *Food Forensics: Methods for Determining the Authenticity of Foodstuffs*, 21 TRENDS IN FOOD SCI. & TECH. 582, 584-88 (2010) (reviewing methods to determine food content); Mark Woolfe & Sandy Primrose, *Food Forensics: Using DNA Technology to Combat Misdescription and Fraud*, 22 TRENDS IN BIOTECHNOLOGY 222, 224 (2004) (describing detection methods for determining food content such as fish species, rice and potato variety, and olive oil provenance).

4. Cf. CLAUDIA GOLDIN & LAWRENCE F. KATZ, *THE RACE BETWEEN EDUCATION AND TECHNOLOGY* (2007) (describing the history of inequality over the twentieth century as a race between education and technology).

5. Answer to Second Amended Complaint, Third Amended Counterclaim, and Third-Party Complaint at ¶ 2, Nestlé Purina Petcare Co. v. Blue Buffalo Co., No. 4:14-cv-00859-RWS (E.D. Mo. May 19, 2015) [hereinafter “Defendant’s Answer”]. Animal byproducts include the non-prime elements of the animal, such as the heads and feet of poultry or brain and bone of livestock. See, e.g., *What is in Pet Food*, ASS’N OF AM. FEED CONTROL OFFICIALS, (last visited Oct. 14, 2016) <http://www.aafco.org/Consumers/What-is-in-Pet-Food> [<https://perma.cc/33X8-3CWG>].

6. These were consolidated in *In re: Blue Buffalo Co., Mktg & Sales Practices Litig.*, No. 4:14-md-02562-RWS (E.D. Mo. 2014).

testing, Purina refused, arguing that “Blue Buffalo should have access to the ingredients contained in its own products.”<sup>7</sup> Once discovery began, Blue found the laboratory in question consisted of one person, who operated out of his own basement, had worked for Purina for 28 years, and used equipment provided by Purina.<sup>8</sup> Unfortunately for Blue, and regardless of its critique of Purina’s testing methodology, discovery also revealed animal byproducts *had* been used because of supplier error, and Blue settled the consumer claims for \$32 million.<sup>9</sup>

A little testing goes a long way. Purina successfully pled its complaint without providing any substantive detail on the testing methodology, which then allowed third-parties to plead injury based on the same uncertain results. This spawned multiple class actions and a truly ugly litigation between companies with common interests in animal welfare.<sup>10</sup> Despite these problems—and these *are* problems—the testing did reveal error in Blue’s supply chain and let concerned consumers receive compensation.

Due to the unique power of testing to drive litigation for good or ill, this article proposes a framework for evaluating product testing at the pleading stage that will aid courts, consumers, and litigants. The framework is based on a simple premise: a complaint with testing should be evaluated according to the same standard as a complaint without testing. Test results may reveal potential injury, but are not sufficient to render an injury plausible any more than artful drafting of a complaint.<sup>11</sup> In particular, courts evaluating testing claims should consider a four-step framework based on traditional tools like *Twombly*, *Iqbal*, and Rule 9(b), along with a basic understanding of statistics. First, courts should require details about product testing to be pled as part of the “how” of consumer fraud under Rule 9. Second, courts should be willing

7. Defendant’s Answer Exhibit T, No. 4:14-cv-00859-RWS (E.D. Mo. May 19, 2015) (“Purina will provide Blue Buffalo with the relevant test results at the appropriate time under the Court’s rules, procedures, and orders. It would seem that Blue Buffalo should have access to the ingredients contained in its own products?”).

8. Defendant’s Answer at ¶ 77, No. 4:14-cv-00859-RWS (E.D. Mo. May 19, 2015) (alleging “Nestlé Purina has been one of Dr. Makowski’s largest clients for nearly three decades, and it purchased much of the equipment in his lab for him”); Deposition of James Makowski, PhD at 86, 90, 95, 126, Defendant’s Answer, No. 4:14-cv-00859-RWS. Purina naturally, and publically, disputed Blue’s characterization of Dr. Makowski’s lab. *E.g.*, Ken Niedziela, *Legal Fight Escalates Between Purina, Blue Buffalo*, VETERINARY PRAC. NEWS (Sept. 22, 2014, 2:36 PM), <http://www.veterinarypracticenews.com/Legal-Fight-Escalates-Between-Purina-Blue-Buffalo/> [<https://perma.cc/964L-Q37F>] (describing disputes over Purina’s testing methods).

9. See Jessica Karmasek, *Federal Judge Approves Blue Buffalo’s \$32 Million Settlement of False Advertising Class Actions*, LEGAL NEWSLINE (May 20, 2016, 9:38 AM), <http://legalnewsline.com/stories/510736267-federal-judge-approves-blue-buffalo-s-32-million-settlement-of-false-advertising-class-actions> [<https://perma.cc/T7FL-H4SX>]. The Blue Buffalo case is discussed further in *infra* Section II.

10. *E.g.*, Jody Godoy, *Purina, Blue Buffalo Told To ‘Play Nice’ In False Ad Fight*, LAW360 (June 17, 2015, 2:00 PM), <http://www.law360.com/articles/668829/purina-blue-buffalo-told-to-play-nice-in-false-ad-fight> [<https://perma.cc/S5WB-VNSZ>] (quoting U.S. District Judge Rodney Sippel, supervising multidistrict litigation stemming from Purina’s late-disclosed testing of Blue Buffalo products, as noting “[i]f not abundantly clear from the last status conference and the court’s most recent orders, the court has reached the limits of its considerable patience with discovery disputes in this case,” and “given their past behavior, the court feels compelled to remind all counsel of their ethical obligations . . . In short, play nice.”).

11. In either the direct or ironic sense. *Compare, e.g.*, Wesley v. Gehrke, No. 194781, 1998 Mich. App. LEXIS 1970, at \*1 (Ct. App. Mich. July 24, 1998) (“A plaintiff may not evade the appropriate limitation period by artful drafting.”) *with* Dolemba v. Ill. Farmers Ins. Co., No. 15-C-463, 2015 U.S. Dist. LEXIS 104314, at \*2 (N.D. Ill. Aug. 10, 2015) (“Although somewhat obscured by the complaint’s artful drafting . . .”). For example, a test result may be statistically significant but of so little practical significance that the alleged injury remains hypothetical.

to screen and dismiss test results based on facially implausible or unscientific testing methods. Third, courts should recognize that the results of some tests may offer no plausible theory of harm to a consumer, even if plausible and properly pled. Finally, the preemptive effect of FDA testing regulations should guide courts resolving claims and plaintiffs planning testing litigation.

The remainder of the Article is organized as follows: the next section provides background on recent food litigation and surveys the use of testing claims in litigation. The third section provides a statistical primer and reviews chemical testing methods used in complaints. The fourth details how pleading standards have been, and should be applied to product testing claims. The final section concludes by looking to the future of product testing and regulation of the food industry.

## II. BACKGROUND

### A. *The New Food Litigation*

Food and litigation have been entwined as long as food and litigation have existed.<sup>12</sup> The surge of interest in unrefined or otherwise “real” food products has not been an exception. Producers met this demand through labeling that appeals to a purveyor of “natural” or similar foodstuffs, which in turn fed a steady stream of labeling-based food litigation, in essence a replacement for rare FDA enforcement actions.<sup>13</sup> As labeling-based litigation expanded, attorneys realized the power of test results: they are quantitative, convey the power of the scientific method, and make a complaint hard to get rid of. At the same time, the ability and availability of testing methods increased, with laboratories only an internet search and FedEx drop box away.

Together, these created a perfect litigation storm for food producers nationwide. In lawsuits spanning the consumer marketplace, plaintiffs began to claim liability based on independent product testing.<sup>14</sup> These plaintiffs typically send products to a laboratory, order tests to be performed on the product, and make the test results the basis for their complaint. The test result is tied to the labeling through a variety of methods, such as finding that nutrient content differs from label statements, showing the presence of a substance not listed on the label, invalidating label statements suggesting pureness, or discovering the quantity of the product differs from that stated on the label.

Although the testing in these lawsuits differs—from DNA testing to chromatography—the suits share several common features. First, the complaints generally give only cursory detail on the alleged testing. For example, one detail repeated as a

12. That is, for a long time. *See, e.g.*, *Scott v. Shepherd*, (1773) 96 Eng. Rep. 525; 2 Wm. Bl. 892 (helping establish the law of torts through an attempt to protect gingerbread from a flaming squib); *Pearcy v. Walter*, (1834) 172 Eng. Rep. 1220; 6 Car. & P. 232 (using drunk driving to help establish the law of negligence); *Thomas v. Winchester*, 6 N.Y. 397 (1852) (helping establish warranty law through mislabeled supplement that contained poison).

13. *See, e.g.*, JENNIFER L. POMERANZ, *FOOD LAW FOR PUBLIC HEALTH*, at ch. 8 “Litigation” (2016).

14. *See* Ann Havelka & Jeff Lingwall, *Get Ready for the 2nd Wave of Food Labeling Litigation*, LAW360, (FEB. 20, 2015), <http://www.law360.com/articles/622279/get-ready-for-the-2nd-wave-of-food-labeling-litigation> (describing product testing in litigation).

mantra is the tests are “independent,” presumably meaning the plaintiffs or their attorneys did not personally operate the laboratory equipment that tested the product. But the complaints generally neglect to specify the laboratory, methodology, detailed results, margin of error, or statistical significance of any testing.<sup>15</sup> The results of the testing are then connected to multiple causes of action through a loose theory of economic loss, along the lines of “the plaintiff overpaid,” or, “the product is worthless because it violates labeling law.” If a contaminant is found in the product, the space between the test result and the economic loss claim is filled with descriptive text alleging the ill-effects of the substance.<sup>16</sup>

The idea of economic loss from mislabeling is then tied to potential causes of action. Litigation based on product testing can be brought under a number of contract, tort, and consumer protection based theories of varying strength. Under a breach of contract theory, the plaintiff alleges the product label formed a contract between purchaser and producer, and the unacceptable deviation from labeling statements breached that contract. Similarly, under a warranty theory, the plaintiff alleges that labeling claims constituted an express warranty, which test results show was violated. Alternatively, the plaintiff claims the test result shows the product is unmerchantable, violating the UCC’s implied warranty of merchantability.

These contract-based theories have a number of weaknesses. Privity requirements under state law are unlikely to be met by a plaintiff’s purchase of the product from a retail store, and courts may question whether a product label constitutes a contractual offer in the first place.<sup>17</sup> An alternative is a tort-based fraud claim, such as common law fraud or negligent misrepresentation. In these, the plaintiff claims the test results show the label misrepresents material facts as to the contents of the product, which the company has either negligently mislabeled or mislabeled with intent to deceive. As with many fraud claims, proving intent and reliance is difficult.<sup>18</sup>

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15. There are exceptions, such as in *Kumar v. Salov N. Am. Corp.*, No. 14-cv-02411-YGR (N.D. Cal. May 23, 2014), in which the plaintiff provides some details about testing such as the type of laboratory used and how the test was performed. The complaint notes, “Plaintiff’s counsel had several bottles of Defendants’ Mock EVOO Products tested by an independent, IOC-accredited laboratory and organoleptic evaluation panel. Each bottle was purchased at well-known California retail stores, packed, and immediately shipped to an IOC-accredited laboratory and sensory panel for analysis. The olive oil was tested prior to the ‘best by’ date indicated by Defendants on the bottles.” Complaint at ¶ 31.

16. These generally do not allege the plaintiff or potential class members suffered these effects. *See, e.g.*, Complaint at ¶¶ 58-62, *Organic Consumers Ass’n v. Post Foods, LLC*, No. 1:16-cv-1640, (D.C. June 22, 2016) (noting link between glyphosate and cancer, disrupted immune function, and liver and kidney damage, without allegation these were suffered by any plaintiff); Complaint at ¶ 10, *Slomski v. The Hain Celestial Group*, No. 8:13-cv-01757 (C.D. Cal. Nov. 6, 2013) (noting that buprofezin causes lesions rodents and the potential neurotoxicity of chlorpyrifos-ethyl without alleging plaintiffs were at risk from these conditions). *See generally* *Hatchendoner v. Genzyme Corp.*, 823 F.3d 724, 732 (1st Cir. 2016) (discussing standing concerning contamination of a medical product and noting “[a] list of horrors then appears, including heart and kidney failure, pain, vision and hearing impairments, and premature death. Utterly absent, however, is any allegation linking the alleged acceleration and contaminant injuries to any specific plaintiff.”).

17. For example, in litigation over nutrient content, nutritional facts statements present expected or average values of nutrients, rather than specific claims for the individual product at issue. *See infra* Section IV(E) (discussing preemption).

18. *E.g.*, *In re Bratten Apparel Corp.*, 21 B.R. 239, 256 (Bankr. S.D.N.Y. 1982) (“Fraud, by its very nature, is difficult to prove, as it is not readily susceptible of ocular observation. It is, by its nature, covert and surreptitious. Indeed, intent to defraud is rarely the object of direct proof, and must be inferred from the evidence in the case

Because of the inherent difficulties in contract and tort-based liability theories for consumer products, the real bite in product testing claims usually comes from state consumer protection laws. Every state has a consumer protection law which prohibits unfair or deceptive advertising, and these often lack the privity, reliance, and intent elements required in common law consumer claims.<sup>19</sup> Florida's Deceptive and Unfair Trade Practices Act is typical. It prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."<sup>20</sup> Because these laws are written broadly, are easy to plead, and specifically concern advertising and consumer rights, they usually provide the vehicle for litigating test results.

### B. *Categorizing Testing Claims*

While testing lawsuits generally follow this structure, testing itself is the Wild West. Some complaints test the defendant's product. Others do not, instead relying on testing reported in the news. Some report the results of the test, while others do not. Some specify that reputable laboratories and testing procedures were used, while others do not. These differences may stem from the recentness of product testing as a litigation strategy, while other differences stem from the advantages of first-filing in the class action setting, and others may reflect deliberate litigation strategy.<sup>21</sup>

To bring some order to this area, this subsection categorizes testing complaints into four categories based on the kind of test and the nature of the allegations.

#### 1. Tests for the quantity of the product

First, testing lawsuits are often based on quantity tests. These take several varieties, such as tests for total quantity of the product, usable quantity, or quantity of a certain ingredient or component nutrient. If any of these quantities test different from what is specified on the label, or if an ingredient is listed on the label but does not test present in the product, the plaintiff alleges they and class members suffered an economic loss. In *Hendricks v. StarKist Co.*, the plaintiff purchased 5-ounce cans of StarKist tuna. "Independent testing by a laboratory retained by Plaintiff's counsel

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dealing with the transaction in question."); Michael Ferry, *Proving Fraud Often Can Be Quite Difficult, Costly*, ST. LOUIS POST-DISPATCH (June 17, 1995) (noting intent "is generally considered . . . to be the hardest part of proving fraud"); Kimberly Bales & Terry L. Fox, *Evaluating a Trend Analysis of Fraud Factors*, 5 J. FIN. & ACCT. 1, 2 (2011) (noting trends in fraud claims and that "[t]he difficulty with proving intent is that it requires determining a person's state of mind").

19. For a survey of state consumer protection laws, see Dee Pridgen, *Wrecking Ball Disguised as Law Reform: Alee's Model Act on Private Enforcement of Consumer Protection Statutes*, 39 N.Y.U. REV. L. & SOC. CHANGE 279, 281-91 (2015) (discussing history of state consumer protection laws); Spencer Weber Waller, *In Search of Economic Justice: Considering Competition and Consumer Protection Law*, 36 LOY. U. CHI. L.J. 631, 636-39 (2005) (discussing private rights of action under state consumer protection law and the link between these laws and antitrust law) (citing Neil W. Averitt & Robert H. Lande, *Consumer Sovereignty: A Unified Theory of Antitrust and Consumer Protection Law*, 65 ANTITRUST L.J. 713 (1997)).

20. FLA. STAT. § 501.204(a) (2015).

21. Like homesteading, the first claim to file within a state may take priority over later-filed claims. Thus, when news of testing results comes, complaints may simply reference the news result rather than testing the plaintiff's product in order to file quickly.

determined that [the cans] contain an average of only 2.35 ounces” of tuna.<sup>22</sup> Based on these allegations, the plaintiff alleged breach of express and implied warranties, unjust enrichment, violation of California consumer protection law, negligent misrepresentation, and fraud.<sup>23</sup>

Next, in *Tye v. Wal-Mart Stores, Inc.*, the plaintiff purchased a can of Pork and Beans, subjected it to unspecified “rigorous scientific testing, including microscopic and chemical analysis,”<sup>24</sup> and allegedly failed to find the presence of any pork in the product.<sup>25</sup> Based on this, the plaintiff brought generic “breach of warranty” and unjust enrichment claims on behalf of a nationwide class, and various state-specific claims on behalf of California, New Jersey, and Pennsylvania subclasses.<sup>26</sup>

Similarly, in *Dougherty v. Source Naturals, Inc.*, the plaintiff purchased a bottle of multivitamins, had a lab test the vitamins for levels of various vitamins in the plaintiff’s product, and alleged a labeling violation based on the results of that test and other results from an internet product evaluation site, “labdoor.com.”<sup>27</sup> Some nutrients tested below the labeled amount, while others tested higher. Based on this, the plaintiff alleged violation of Missouri consumer protection law and unjust enrichment.<sup>28</sup>

Finally, a testing lawsuit might complain about the quantity of *usable* product, rather than the amount of a product, ingredient, or nutrient itself. In a flurry of lawsuits against Genentech for its cancer drug Herceptin, plaintiffs alleged that the usable quantity of the drug once reconstituted was less than the labeled amount.<sup>29</sup> Based on this, the plaintiff alleged breach of warranties, violation of consumer protection law, and unjust enrichment.<sup>30</sup>

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22. Complaint at ¶ 2, *Hendricks v. Starkist Tuna Co.*, No. 4:13-cv-00729 (N.D. Cal. Feb. 19, 2013) (plaintiff’s counsel tested the tuna “according to the methods specified by 21 C.F.R. § 161.190(c)” which details testing methods for tuna quantity); see also Complaint at ¶¶ 1-8, *Magier v. Trader Joe’s Co.*, No. 1:16-cv-00043 (S.D.N.Y. Jan. 5, 2016) (raising similar allegations about Trader Joe’s canned tuna).

23. Complaint at ¶ 4, *Hendricks v. Starkist Tuna Co.*, No. 4:13-cv-00729. By “California consumer protection law,” I mean alleged violations of California’s unfair competition law, CAL. BUS. & PROF. CODE § 17200 *et seq.*, deceptive advertising law, CAL. BUS. & PROF. CODE § 17500 *et seq.*, and the California Consumers Legal Remedies Act, CAL. CIV. CODE § 1750 *et seq.*

24. Second Amended Complaint at ¶ 55, *Tye v. Wal-Mart Stores Inc.*, No. 8:15-cv-01615 (DOC-JCG) (C.D. Cal. May 20, 2016).

25. Order Granting in Part Motion to Dismiss Plaintiffs’ First Amended Class Action Complaint, *Tye v. Wal-Mart Stores Inc.*, No. 8:15-cv-01615 (DOC-JCG) (C.D. Cal. Apr. 26, 2016).

26. Complaint at ¶¶ 15-42, *Tye v. Wal-Mart Stores Inc.*, No. 8:15-cv-01615 (DOC-JCG) (C.D. Cal. Oct. 7, 2015).

27. Complaint at ¶ 17, *Dougherty v. Source Naturals, Inc.*, No. 4:15-cv-00574 (E.D. Mo. Feb. 11, 2015); Defendant Source Naturals, Inc.’s Motion to Dismiss at 8, *Dougherty v. Source Naturals, Inc.*, No. 4:15-cv-00574-RLW (E.D. Mo. Apr. 10, 2015).

28. Petition and Jury Demand at ¶ 29-38, *Dougherty v. Source Naturals, Inc.*, No. 4:15-cv-00574. See also Complaint at ¶¶ 25-26, *Klingberg v. Whole Foods Market, Inc.*, No. 1:17-cv-00138 (N.D. Ill. Jan. 9, 2017) (alleging test of Whole Foods’ St. John’s Wort product revealed levels of hypericin “a little above 30% of the label claim”).

29. *E.g.*, Complaint at 7, *Comanche Cty. Mem’l Hosp. v. Genentech, Inc.*, No. 3:16-cv-02498-JSC (N.D. Cal. May 9, 2016).

30. *Id.* at 10-14.



## 2. Tests for the quality of the product

Next, some complaints examine the nature of the product itself. In *Kumar v. Salov North America Corp.*, the plaintiff purchased a bottle of Filippo Berio extra-virgin olive oil.<sup>31</sup> Olive oil has precise, regulated standards for various quality claims, ranging from “extra virgin olive oil” to “virgin olive oil” to simply “olive oil,” based on the production method and the chemical composition of the oil.<sup>32</sup> A number of tests are employed in making this distinction, including chemical analysis and tests for flavor.<sup>33</sup> The plaintiff had her bottle tested, found it did not meet the stringent standards required to be labeled “extra virgin,” and alleged violation of California consumer protection law, breach of contract, breach of the covenant of good faith and fair dealing, and fraud.<sup>34</sup>

Similarly, in *Fonseca v. Goya Foods Inc.*<sup>35</sup> and *Fonseca v. Vigo Importing Co.*,<sup>36</sup> the plaintiff purchased a variety of octopus products (such as Goya’s “Octopus in Olive Oil” and Vigo’s “Spanish Octopus in Soy and Olive Oil”), hired a lab to perform DNA testing on the meat, and claimed the products “are actually jumbo squid and not octopus.”<sup>37</sup> Based on this, the plaintiff claimed breach of warranties, unjust enrichment, negligent misrepresentation, fraud, and violation of various California statutes. When Goya moved to dismiss the complaint for lack of detail on testing, the plaintiff responded by noting “those are topics Goya can probe in discovery.”<sup>38</sup> While still in litigation, Goya quietly changed its product label from “Octopus in Olive Oil” to “Jumbo Squid in Olive Oil – Octopus Style.”<sup>39</sup>

*Gubala v. HBS International Corp.* represents a whole class of “protein spiking” lawsuits against supplement producers.<sup>40</sup> In these lawsuits, the plaintiffs allege that producers calculate protein content using a test for the total amount of nitrogen in the product, a test that improperly counts “nitrogen-containing free-form amino acids” as protein.<sup>41</sup> In *Gubala*, the plaintiffs performed an allegedly superior test for protein content, the “Protein Digestibility Corrected Amino Acid Score” test, and

31. Complaint at 13, *Kumar v. Salov N. Am. Corp.*, No. 14-cv-02411-YGR (N.D. Cal. May 23, 2014).

32. See, e.g., Havelka & Lingwall, *supra* note 14.

33. See, e.g., E. N. FRANKEL ET AL., REPORT: EVALUATION OF EXTRA-VIRGIN OLIVE OIL SOLD IN CALIFORNIA 3-6 (U.C. Davis Olive Center, April 2011).

34. Complaint at 16-25, *Kumar v. Salov N. Am. Corp.*, No. 14-cv-02411-YGR.

35. Complaint at 2, *Fonseca v. Goya Foods Inc.*, No. 5:16-cv-02559-LHK (N.D. Cal. May 11, 2016).

36. *Fonseca v. Vigo Importing Co.*, No. 5:16-cv-02055-EJD (N.D. Cal. Apr. 19, 2016).

37. Complaint at 2, *Fonseca v. Goya Foods Inc.*, No. 5:16-cv-02559-LHK.

38. Plaintiff’s Memorandum of Points and Authorities in Opposition to Defendant Goya Foods, Inc.’s Motion to Dismiss Complaint at 5, No. 5:16-cv-02559-LHK (N.D. Cal. Aug. 15, 2016).

39. Compare, e.g., *Goya Octopus in Olive Oil*, AMAZON.COM, [https://www.amazon.com/Goya-Pulpo-Octopus-Oil-Oz/dp/B005F5K6L8/ref=sr\\_1\\_1\\_s\\_it?s=grocery&ie=UTF8&qid=1471968468&sr=1-1&keywords=goya+octopus](https://www.amazon.com/Goya-Pulpo-Octopus-Oil-Oz/dp/B005F5K6L8/ref=sr_1_1_s_it?s=grocery&ie=UTF8&qid=1471968468&sr=1-1&keywords=goya+octopus) [<https://perma.cc/7BUY-6ECU>] (visited Aug. 23, 2016), with *Jumbo Squid in Olive Oil–Octopus Style*, JEWEL-OSCO, <http://www.jewelosco.com/pd/Goya/Jumbo-Squid-in-Olive-Oil-Octopus-Style/4-oz/041331036375/> [<https://perma.cc/2ZN6-779D>] (visited Aug. 23, 2016) (showing identical label image and SKU).

40. *Gubala v. HBS Int’l Corp.*, No. 14-C-9299, 2016 U.S. Dist. LEXIS 58988 (N.D. Ill. May 4, 2016). For other examples, see *infra* Section IV (discussing preemption of protein spiking cases).

41. *Id.* at \*4.

found results that showed a lower amount of “true” protein in the product. Based on this, they claimed breach of warranties and unjust enrichment on behalf of HBS.<sup>42</sup>

### 3. Tests for the presence of substances not labeled

Next in this taxonomy are tests for the presence of substances not on the label. In these suits, rather than testing for whether the label statements as to quality and nutrition content are true, the plaintiff tests for the presence of some substance not listed as an ingredient. In *Nestlé Purina Petcare Co. v. Blue Buffalo Co.*, and the class actions it spawned discussed in the introduction, Purina sued rival producer Blue Buffalo based on “[t]esting from an independent laboratory” that allegedly showed the presence of animal byproducts in the pet food.<sup>43</sup> Blue Buffalo’s labels did not list animal byproducts as an ingredient, and so Purina alleged violations of the Lanham Act, common law unfair competition, and unjust enrichment.<sup>44</sup>

Hunting for substances not on the label is not limited to pet food. In *Cooper v. Quaker Oats Co.*<sup>45</sup> and a series of similar lawsuits,<sup>46</sup> the plaintiff tested “natural” oat products for the presence of a herbicide used in production of oats. The plaintiff alleged “quantitative testing revealed that Quaker Oats contain glyphosate,”—otherwise known as Roundup—and that “[d]iscovery of the true nature of the ingredients requires knowledge of chemistry and access to laboratory testing that is not available to the average reasonable consumer.”<sup>47</sup> Without other detail about the test, the plaintiff alleged violation of California consumer protection law, false advertising, unfair competition, and breach of an express warranty.<sup>48</sup> Later reporting disclosed the testing was performed using liquid chromatography-mass spectrometry, which is discussed in the following section.<sup>49</sup>

Moving from oats to wine, the plaintiff in *Charles v. Wine Group, Inc.* alleged “three separate testing laboratories skilled in arsenic testing” found “dangerously high levels of inorganic arsenic” among the wines of a variety of California producers.<sup>50</sup> Without furnishing substantive details on the testing methodology, the plaintiff alleged breach of California consumer protection law, unjust enrichment, negligent misrepresentation, and breach of the implied warranty of merchantability.<sup>51</sup>

42. *Id.* at \*17-20.

43. Complaint at 1, *Nestlé Purina Petcare Co. v. Blue Buffalo Co.*, No. 4:14-cv-00859-RWS (E.D. Mo. May 6, 2014).

44. *Id.* at 25-28. This case was brought as producer-on-producer, but spawned multiple consumer class actions that relied on the testing from the Purina lawsuit.

45. *Cooper v. Quaker Oats Co.*, No. 3:16-cv-02364-LB (N.D. Cal. Apr. 29, 2016).

46. *Gibson v. Quaker Oats Co.*, No. 16-cv-04853 (N.D. Ill. May 2, 2016); *Cooper*, No. 3:16-cv-02364-LB; *Daly v. Quaker Oats Co.*, No. 16-cv-02155 (E.D.N.Y. Apr. 29, 2016); *Jaffee v. Quaker Oats Co.*, No. 16-cv-21576 (S.D. Fla. May 3, 2016).

47. Complaint at 13, 16, No. 3:16-cv-02364-LB.

48. *Id.* at 26-33.

49. Stephanie Strom, *Quaker Oats’ 100% Natural Claim Questioned in Lawsuit*, N.Y. TIMES, May 1, 2016. According to the Times, the test results found 1.18 parts per million glyphosate (the regulatory tolerance level is 30 parts per million).

50. Complaint at 3, *Charles v. Wine Group Inc.*, No. BC576061 (Super. Ct. Cal. Mar. 19, 2015).

51. *Id.* at 24-27.

## 4. Testing complaints that fail to test the plaintiff's product

As a subset of tests for foreign material, many lawsuits are now based on testing that did not concern the plaintiff's actual product. These are usually filed after public reports of some contamination to a product, such as the consumer class actions spawned in the Blue Buffalo litigation. In these, as in *Hackman v. Kraft Heinz Food Co.*,<sup>52</sup> the plaintiff alleged that Kraft's "100% Parmesan Cheese" actually includes up to 4% cellulose, contrary to the label.<sup>53</sup> The plaintiff discovered this, not through her own testing, but through a Bloomberg news article discussing the use of cellulose in Parmesan.<sup>54</sup> She then purchased the product and "has directed the Parmesan Cheese to be tested by an independent laboratory."<sup>55</sup> She "expects . . . that the results will show that the product contains filler, including an amount of cellulose that is deceptive to the consumer."<sup>56</sup> Based on this, the plaintiff alleged violation of District of Columbia consumer protection law, breach of express warranty, and breach of the implied warranty of merchantability.<sup>57</sup>

Similarly, in *Slomski v. Hain Celestial Group, Inc.*, the plaintiff purchased bags of "natural" tea produced by Hain, referenced a report indicating that some bags had been found to contain pesticide residue, and sued.<sup>58</sup> In a kind of dueling lack-of-results, the complaint provided no substantive details on testing, while also calling out Hain for publicizing its own opposite-concluding test results without details.<sup>59</sup> Based on the apparent findings of this report, the plaintiff alleged violation of California consumer protection law, and breach of express warranty.<sup>60</sup>

Next, in *Lucido v. Nestlé Purina Petcare Co.*, the plaintiff purchased bags of pet food, and referenced product testing by an advocacy group that found the presence of mycotoxins (a metabolite produced by fungus).<sup>61</sup> Based on this test, the plaintiff alleged breach of express and implied warranties, negligence, negligent misrepresentation, strict liability, and violation of California consumer protection law.<sup>62</sup>

52. Complaint at 3-4, *Hackman v. Kraft Heinz Food Co.*, No. 2:16-cv-00328-MRH (W.D. Pa. Mar. 18, 2016).

53. *Id.* FDA allows the use of cellulose as an anti-caking agent in grated cheese. See 21 C.F.R. § 133.146.

54. Lydia Mulvany, *The Parmesan Cheese You Sprinkle on Your Penne Could Be Wood*, BLOOMBERG (Feb. 16, 2016, 4:00 AM), <http://www.bloomberg.com/news/articles/2016-02-16/the-parmesan-cheese-you-sprinkle-on-your-penne-could-be-wood> [https://perma.cc/R63C-VZJA].

55. Complaint at 5, No. 2:16-cv-00328-MRH.

56. *Id.* (emphasis added).

57. *Id.* at 8-11.

58. Complaint at 3-9, *Slomski v. Hain Celestial Group, Inc.*, No. 8:13-cv-01757-AG-AN (C.D. Cal. Nov. 6, 2013). The report plaintiff referenced was from a study Glauco Research Group initiated to criticize Hain and recommend selling its stock. See Samantha Bonar, *High Levels of Pesticides Found in Celestial Seasonings Tea*, LA WEEKLY (June 17, 2013), <http://www.laweekly.com/restaurants/high-levels-of-pesticides-found-in-celestial-seasonings-tea-2895931> [https://perma.cc/J96K-9JBX].

59. Complaint at 9, *Slomski*, No. 8:13-cv-01757-AG-AN ("Defendant has not disclosed the actual test results on which it relied . . . and, on information and belief, has claimed that the results constitute proprietary information.") (internal quotations omitted).

60. *Id.* at 15-19.

61. Complaint at 6, *Lucido v. Nestlé Purina Petcare Co.*, No. 3:15-cv-00569-LB (N.D. Cal. Feb. 5, 2015) ("The Association for Truth in Pet Food conducted testing of Beneful Original and found that it contained dangerous levels of mycotoxins.")

62. *Id.* at 9-16.

Finally, in *In re Whole Foods Market, Inc.*, plaintiffs claimed Whole Foods 365 Everyday Value Plain Greek Yogurt contained more sugar than labeled “[a]ccording to six tests conducted by Consumer Reports magazine.”<sup>63</sup> Despite coordinating eleven class actions against Whole Foods, the plaintiffs failed to test any of the plaintiff’s purchases,<sup>64</sup> and brought claims of “violations of various state consumer protection and unfair competition statutes as well as claims for breach of warranty, unjust enrichment, negligent misrepresentation, and for other equitable remedies.”<sup>65</sup>

### III. INTERPRETING PRODUCT TESTING RESULTS

Understanding both the results reported in common consumer product testing class actions, and the policy implications inherent in accepting those test results, requires a basic understanding of statistics and principles of chemical testing. This Section provides a brief background on basic statistical concepts and examines several major chemical testing techniques.

#### A. Statistical Primer

Understanding typical product testing and the regulations surrounding it does not take an advanced degree in statistics, although some background in statistics is useful. Even if statistical concepts like formal hypothesis testing are not used in a product test, the language of statistics drives the conceptual interpretation of test results. This subsection introduces the basic statistical concepts needed to discuss test results and the regulatory environment of testing.

First is the idea of summary statistics.<sup>66</sup> A primary role of statistics is to summarize data in an informative fashion, which serves as a springboard for understanding the concepts behind those numbers. This is often done through a set of descriptive statistics that summarize key parts of the data, such as its central tendency and variability.<sup>67</sup> Each of these concepts has many different ways of being calculated. For instance, we might measure the center of a set of data by simply ordering the observations and picking the middle number—that is, we might calculate the median. Alternatively, we might add up all the numbers and divide by how many numbers there are—that is, we might calculate the arithmetic average or mean.

The variability of the data can also be measured in multiple ways. The most common are standard deviation and variance.<sup>68</sup> The standard deviation represents the average difference between each number in the dataset and the arithmetic mean.

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63. Order at 2, *In Re Whole Foods Mkt., Inc.*, No. A-14-MC-2588-SS, MDL NO. 2588, at ¶¶ 30-31 (W.D. Tex. Feb. 12, 2016).

64. *Id.* at ¶ 2.

65. *Id.* at ¶ 3. The claims were dismissed as preempted by federal law. *See infra* Section IV.

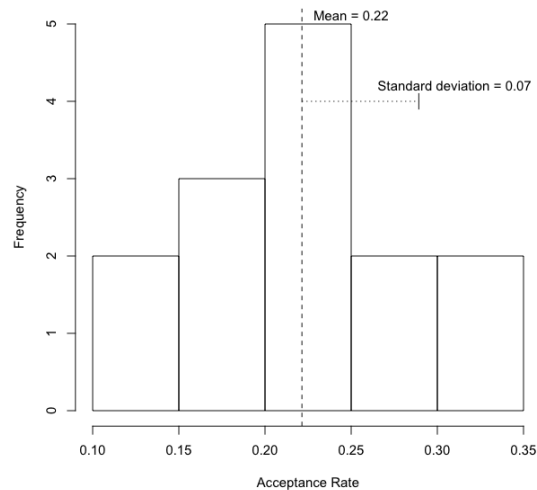
66. The technical definition of a statistic is “[a] function of observable random variables . . . which does not depend on any unknown parameters.” LEE J. BAIN & MAX ENGELHARDT, INTRODUCTION TO PROBABILITY AND MATHEMATICAL STATISTICS 264 (1992).

67. For a more technical version of this discussion, *see id.* at 69-73, 290-91 (discussing the technical definitions of the median and sample moments).

68. To be precise, what is commonly used is the sample standard deviation and sample variance. *See id.* at 160-61.

As a rule of thumb, about 66% of data fall within one standard deviation of their mean, and 90% of data fall within two standard deviations of their mean. The “variance” of a dataset is the square of the standard deviation, though I generally use the term in its colloquial sense of “variability.”

These ideas are illustrated simply with an example dataset. Consider the following 14 numbers: 0.10, 0.11, 0.18, 0.19, 0.20, 0.21, 0.22, 0.22, 0.22, 0.23, 0.28, 0.30, 0.31, and 0.33, which represent acceptance rates at T14 law schools.<sup>69</sup> The average rate is 0.22, and the standard deviation is 0.07. A common way to illustrate data graphically is through a histogram—a chart that sorts the data into a number of bins and then notes the frequency at which observations occur in each bin. A histogram of the T14 data, annotated with summary statistics, looks like this:



A smaller standard deviation (less variability) would mean the data are grouped closer to 0.22, and a larger standard deviation (more variability) would mean the data are grouped farther away from 0.22.

These numbers summarize the data, but how informative they are depends on the underlying nature of the data. For example, law school acceptance rates are driven by two factors: the number of applicants and the number accepted. The acceptance rate by itself tells us little about the selectivity of the school vis-à-vis the national applicant pool, because of selection bias in the choice of which schools to send an application. Because many students choose not to apply to some law schools, particularly if the chance of acceptance appears low, the “true” selectivity rate versus the average law school applicant differs from the reported rate. In other words, because a school has a 20% acceptance rate does not mean the average law school applicant faces a 20% chance of acceptance if choosing to apply.

In the same way, details reported in a product test reflect the underlying data. For example, in a typical test for the quantity of an ingredient or nutrient, there are

69. *T14 Law Schools*, START-CLASS.COM, [http://law-schools.startclass.com/saved\\_search/T14-Law-Schools](http://law-schools.startclass.com/saved_search/T14-Law-Schools) [<https://perma.cc/9C8F-X34K>] (last visited June 20, 2016).

at least three sources of variance. First, there is variance inherent in the ingredient itself. For example, nutrient content of a vegetable varies according to a multitude of factors, such as growing conditions, genetic factors particular to the individual plant, time since harvest, and conditions of storage.<sup>70</sup> Second, the variance inherent in manufacturing processes. When ingredients are extracted, baked, boiled, chopped, concentrated, and otherwise combined into a finished product, this process adds further variability, because no production run will ever be precisely the same due to, e.g., fluctuations in temperature in an oven, differences in personnel, and innumerable other factors.<sup>71</sup> Finally, results of a test reflect the natural variability in a test *itself*. No matter the method, testing is a process that inherently creates variability. Product is crushed, melted, or vaporized, run through machinery, and handled by laboratory technicians. Even identical samples may generate different results based on the inherent variability of the test.

If we combine the idea of central tendency and variability, we arrive at a powerful statistical principle that bears on why many testing claims are preempted by federal law.<sup>72</sup> The variability associated with an average will be lower than the variability from any single observation. Likewise, the more observations one has, the lower the variability of the average will be. For example, if you flip a fair coin four times and record the proportion of flips that land on heads, there is a good chance it might be either 0.0 (no heads) or 1.0 (all heads).<sup>73</sup> But if you flip that coin a thousand times, there is a near-zero probability the total proportion heads will be either zero or one.<sup>74</sup> Assuming the coin is fair, the average from a thousand flips will be quite close to 0.5, because the variability of the average decreases with the size of the sample. The same principle applies when testing food: the larger the sample size, the less variability will be exhibited by the results of the analysis.

## B. Chemical Testing

### 1. Classical methods

With those statistical principles in mind, this subsection describes chemical testing methods used in food litigation. Chromatography is one of the most commonly used techniques to separate and isolate organic molecules in a compound, making it useful for examining the components in food.<sup>75</sup> The technique was discovered by

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70. FDA recognizes that “selected nutrients in some foods may undergo changes due to various factors (e.g., time after harvest or catch, processing, manufacture, conditions of transport).” FDA, *Guidance for Industry: Nutrition Labeling Manual - A Guide for Developing and Using Data Bases* (1998), [http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063113.htm#design\\_2](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063113.htm#design_2).

71. See, e.g., MERTON R. HUBBARD, *STATISTICAL QUALITY CONTROL FOR THE FOOD INDUSTRY 2* (2003) (“It is generally known that perfection is not possible . . . we must accept the fact that variability does exist . . .”).

72. See *infra* Section IV(E).

73. The probabilities of each is about six percent, and can be calculated from the binomial distribution. See BAIN, *supra* note 66, at 91.

74. The probability of seeing no heads out of a thousand coin flips is  $9.33 \times 10^{-302}$ , which is zero for practical purposes.

75. See ANDREAS MANZ, PETRA S. DITTRICH, NICOLE PAMME, & DIMITRI IOSSIFIDIS, *BIOANALYTICAL CHEMISTRY* 36 (2015).

Russian scientist Mikhail Tswett at the turn of the twentieth century, and involves dissolving the substance to be tested in a fluid, which is then passed through various materials.<sup>76</sup> Because the components of the substance will move through the materials at varying speeds, they separate and require differing amounts of time to hit a receptor.<sup>77</sup> The times at which they hit the detector are recorded, and the result—called a chromatograph—allows identification of the component substances. An example of chromatographic output used in litigation is a test for the presence of amino acids in the *Gubala* protein powder litigation, discussed above.<sup>78</sup>

A variant of chromatographic analysis called liquid chromatography-mass spectrometry combines its separating powers with mass spectrometry. Since some substances have similar chromatographic profiles, chromatography is often combined with another detection method, such as mass spectrometry.<sup>79</sup> Mass spectrometry ionizes molecules from the substance to be tested, puts them in a vacuum to create distance between ions, then separates the ions by the ratio of their mass to their charge with a mass analyzer. A detector records this value, which allows identification of component substances.<sup>80</sup> This was used to detect the presence of glyphosate in the *Quaker Oats* litigation.<sup>81</sup>

## 2. Molecular recognition tests

Another set of common chemical testing techniques use the biomolecular recognition properties of molecules—that is, the ability of molecules to form keys and locks.<sup>82</sup> One example used in litigation is enzyme-linked immunosorbent assay testing, or ELISA. Immunoassay testing relies on the properties of antibodies. Because antibody molecules bind themselves to specific antigens, they can be used to detect the presence of particular molecules in a sample.<sup>83</sup> A common example is a pregnancy test—the hormone human chorionic gonadotropin appears early in pregnancy. This binds with an antibody on the pregnancy test strip, which changes color.<sup>84</sup>

ELISA is one of the most popular immunoassay formats. In essence, it fixes the antibody or the antigen to an assay plate, and uses an enzyme to detect binding between the antibody and the antigen.<sup>85</sup> A substrate is then added, which reacts with the enzyme and changes color based on the amount of the antigen.<sup>86</sup> The color

76. *Id.* at 31.

77. *Id.*

78. The plaintiff's chromatographs were reported in Complaint Exhibit A, *Gubala v. CVS Pharm., Inc.*, No. 1:14-cv-09039, (N.D. Ill. Mar. 15, 2016).

79. ROBERT E. ARDREY, LIQUID CHROMATOGRAPHY – MASS SPECTROMETRY: AN INTRODUCTION 33 (2003).

80. MANZ, *supra* note 75, at 93-95.

81. Strom, *supra* note 49.

82. MANZ, *supra* note 75, at 143.

83. See LARRY H. STANKER & ROSS C. BEIER, *Introduction to Immunoassays for Residue Analysis: Concepts, Formats, and Applications*, in IMMUNOASSAYS FOR RESIDUE ANALYSIS: FOOD SAFETY 2, 3-5 (1996).

84. MANZ, *supra* note 75, at 154-55.

85. See STANKER, *supra* note 83, at 7-8.

86. *Id.*

change is then quantified, such as by using a spectrometer. Compared to chromatography or mass spectrometry, ELISA may perform a similar role, such as detecting glyphosate in Quaker Oats products,<sup>87</sup> but is relatively inexpensive and simple to perform.<sup>88</sup> The cost of this convenience is that results may be less accurate than classical methods such as chromatography.<sup>89</sup>

Finally, DNA testing is a form of molecular recognition test that can be used to identify the presence of substances in a product. This type of chemical testing has received ample treatment in the literature on criminal forensics, family law, and immigration, and relies on many of the same principles as immunoassay tests.<sup>90</sup> DNA testing is based on the remarkable power of the DNA molecule to self-replicate. Copies of the molecule are made through a chemical process, such as polymerase chain reaction, which “melts” the DNA by splitting it into two strands, which become templates for “primer” molecules to attach. These new strands of DNA can then be split and reformed until multiple copies exist.<sup>91</sup> These copies can then be tested for matching with target DNA fragments in a process similar to immunosorbent assay testing.<sup>92</sup>

#### IV. EVALUATING PRODUCT TESTING CLAIMS

This Section motivates and describes the legal challenges inherent in evaluating testing claims and offers a framework for evaluating those claims. In a product testing lawsuit, (1) details on testing should be alleged as part of the initial pleading, as part of Rule 9’s particularity requirement for claims involving fraud, (2) a *Daubert*-like standard should apply to filter unscientific “testing” at the Rule 12 stage, as part of the *Twombly* and *Iqbal* plausibility requirements, (3) claims that have no practical significance should be dismissed under either Rule 12(b)(1) (lack of standing) or Rule 12(b)(6) (no plausible injury), and (4) whether claims are preempted by federal law should be evaluated.<sup>93</sup>

87. The Alliance for Natural Health USA, *Glyphosate Levels in Breakfast Foods: What is safe?* (Apr. 19, 2016), <http://www.anh-usa.org/wp-content/uploads/2016/04/ANHUSA-glyphosate-breakfast-study-FINAL.pdf>.

88. Didier Leveux, *Immunodiagnostic Technology and Its Applications*, in *ADVANCES IN FOOD DIAGNOSTICS* 211 (Leo M. L. Nollet & Y. H. Hui eds., 2007).

89. See STANKER, *supra* note 83, at 2 (“Traditionally, residue analysis has relied upon classical analytical methods such as chromatography . . . Such methods require highly trained individuals to operate sophisticated instruments and interpret complex . . . results. These features make most traditional residue methods highly accurate, but they also make them time consuming, costly, and generally not adaptable to use in the field.”); EPA, *Nutrient Pollution Policy and Data*, <https://www.epa.gov/nutrient-policy-data/detection> (last visited Aug. 1, 2016) (noting that for some applications ELISA is “sensitive, rapid, and suitable for large-scale screening but [is] predisposed to false positives”).

90. E.g., Kerry Abrams and Brandon L. Garrett, *DNA and Distrust*, 91 NOTRE DAME L. REV. 757, 761 (2015) (discussing conceptual modes of DNA’s legal treatment); Lilda P. Barata, Helene Starks, Maureen Kelley, Patricia Kuszler, & Wylie Burke, *What DNA Can and Cannot Say: Perspectives of Immigrant Families About the Use of Genetic Testing in Immigration*, 26 STAN. L. & POL’Y REV. 597, 601 (2015) (advising, e.g., that “immigration lawyers be educated about the test, the testing process, and the potential positive and negative consequences of test results so they can better advise their clients”); Brandon L. Garrett, *DNA and Due Process*, 78 FORDHAM L. REV. 2919, 2920-25 (2010) (describing treatment of DNA testing by courts).

91. See MANZ, *supra* note 75, at 181.

92. *Id.* at 166-67.

93. This Section is written referencing federal standards, because most large class actions are removable under the Class Action Fairness Act, and because class action standards under state law are often analyzed with similar principles.



### A. Pleading Standards Versus Technology

The law moves at a glacial pace compared to technological change, and this is particularly true of procedure.<sup>94</sup> Major changes in pleading doctrines come rarely, and even incremental changes in common law analysis take time.<sup>95</sup> In contrast, testing technology changes quickly.<sup>96</sup> DNA testing evolved from a costly, cumbersome procedure to a routine analysis in the space of two decades, a heartbeat in terms of the law.<sup>97</sup> Advances in testing technology for foodstuffs have been a “technical ‘tour de force’” in recent years, reflecting advances in both interest and technology.<sup>98</sup> To site just several examples, in 2016 a company launched an immunoassay ELISA test capable of rapidly detecting up to 0.1 parts per *billion* ethoxyquin in meat.<sup>99</sup> Lectin chip arrays can now distinguish between the proteins in cow’s milk and buffalo milk, to examine whether buffalo mozzarella has been cheapened.<sup>100</sup> Stable isotope analysis can determine where food was grown, and even how the food was produced.<sup>101</sup>

These advances are admirable, turning food scientists into crime scene investigators and providing means to independently verify the content of countless products, but they come at a cost. At a sufficiently high level of resolution, all food is contaminated, whether from contact with particulates in the air, from packaging, or from the inherently variable nature of its production.

As detailed below, pleading standards often fail to provide sufficient screening mechanisms for early resolution of such claims. To avoid the possibility of expensive discovery and negative publicity that accompanies consumer class actions, defendants may opt to settle claims of questionable merit.<sup>102</sup> As increasingly powerful testing

94. Although cellphones existed since the 1980s, the Supreme Court did not require warrants before searching until 2014. *Riley v. California* 134 S. Ct. 2473, 2485 (2014) (requiring that officers “generally” obtain a warrant before searching a cellphone). Or, despite GPS technology existing for consumer use since at least mid-2000s, the Court waited until 2012 before famously applying eighteenth century tort law to decide whether GPS tracking constitutes a search. *United States v. Jones*, 132 S. Ct. 945, 949 (2012).

95. *E.g.*, fifty years passed between *Conley* and *Twombly*. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Conley v. Gibson*, 355 U.S. 41 (1957).

96. *E.g.*, *Nat’l Res. & Dev. Corp. v. Varian Assocs.*, 822 F. Supp. 1121, 1122-23 (1993) (describing “[m]odern spectroscopy”); MICHAEL LYNCH et al., *TRUTH MACHINE: THE CONTENTIOUS HISTORY OF DNA FINGERPRINTING* (2008); Kelly Virkler & Igor K. Lednev, *Analysis of Body Fluids for Forensic Purposes: From Laboratory Testing to Non-Destructive Rapid Confirmatory Identification at a Crime Scene*, 188 *FORENSIC SCI. INT’L* 1 (2009) (describing advances in spectroscopic identification).

97. *See, e.g.*, John D. Groopman et al., *Molecular Biomarkers for Human Liver Cancer*, in I. GLENN SIPES et al., *COMPREHENSIVE TOXICOLOGY* 249, 256 (2002) (describing a “100 fold increase in sensitivity” in DNA-related testing).

98. Primrose et al., *supra* note 3, at 582-83.

99. BIOO SCIENTIFIC, *Bioo Scientific Launches ELISA for Screening of Ethoxyquin in Fishmeal, Fish, Shrimp, Feed and Meat* (Mar. 16, 2016), <http://www.biooscientific.com/Bioo-Scientific-Launches-ELISA-for-Screening-of-Ethoxyquin-in-Fishmeal-Fish-Shrimp-Feed-and-Meat>.

100. Primrose et al., *supra* note 3, at 587.

101. *Id.* at 588.

102. On the risk of abusive litigation and disproportionate discovery costs, see *e.g.*, *Twombly*, 550 U.S. at 559 (quoting Memorandum from Paul V. Niemeyer, Chair, Advisory Committee on Civil Rules, to Hon. Anthony J. Scirica, Chair, Committee on Rules of Practice and Procedure (May 11, 1999), 192 F.R.D. 354, 357 (2000)) (“[D]iscovery accounts for as much as 90 percent of litigation costs when discovery is actively employed.”). Recent changes to Rule 26 requiring “proportionality” in discovery may be helpful in this regard, but past experience has shown that proportionality in discovery is easy to discuss but difficult to implement. *See, e.g.*, Hon. Elizabeth D. Laporte and Jonathan M. Redgrave, *A Practical Guide to Achieving Proportionality Under New Federal Rule of Civil Procedure 26*, 2015

brings litigation over smaller amounts of contamination, consumers risk losing labeling information that would otherwise usefully guide purchasing decisions.

### B. Pleading Testing-Based Fraud Claims with Particularity

This Section argues for a *Daubert*-like gatekeeping standard to apply at the Rule 12 stage when initial pleadings are based on product testing.<sup>103</sup> It also argues that the mechanisms for applying this standard already exist—through the particularity requirement for pleading fraud under Rule 9(b), the pleading standards in *Twombly* and *Iqbal*, and traditional principles of standing. Altogether, these provisions provide screening mechanisms that minimize litigation costs by keeping pseudo-scientific testing out of court and by filtering claims in which testing results have no practical significance.

There is an extensive literature on the policy justifications for the gatekeeping role of judges in traditional *Daubert* motions. *Daubert* keeps pseudoscience out of court,<sup>104</sup> minimizes litigation costs by providing standards for the admission of scientific evidence before trial,<sup>105</sup> and tempers the type of scientific evidence brought to court.<sup>106</sup> Whether *Daubert* adequately meets these ambitions is controversial, but, at the least, it provides an enabling mechanism for pre-trial scientific screening.<sup>107</sup>

Similar justifications apply to the need for attentive analysis of testing claims at the beginning of a suit. Scrutiny of alleged test results for reliability and practical injury early in a suit reduces the risk of abusive litigation based on pseudoscientific test

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FED. CTS. L. REV. 19, 22 (2015) (discussing the addition of rules to help with disproportionate discovery in 1983 and noting “[n]otwithstanding this watershed moment in the evolution of the Federal Rules, many litigants have seemingly been unable to master these proportionality concepts”); Henry S. Noyes, *Good Cause Is Bad Medicine For The New E-Discovery Rules*, 21 HARV. J. L. & TECH. 49, 81 (2007) (discussing the 2000 amendments to the Rules affecting discovery and noting that “courts and practitioners have ignored the amendments altogether”).

103. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). If not at the 12(b)(6) stage, certainly such a standard should apply at class certification. See Meredith M. Price, *The Proper Application of Daubert to Expert Testimony in Class Certification*, 16 LEWIS & CLARK L. REV. 1349, 1351-54 (2013).

104. E.g., *Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 606 (1998) (discussing *Daubert* and noting “the Court cannot abdicate its role as ‘gatekeeper’ and subject the jury unfairly to confusing and misleading ‘pseudoscientific’ research”); *Miller v. Eldridge*, 146 S.W.3d 909, 919 (Ky. 2004) (“The *Daubert* factors were designed to make distinctions between science and pseudo-science, between, for example, astronomy and astrology.”). See generally, *West Virginia v. Woodall*, 385 S.E.2d 253, 260 (W. Va. 1989) (“Pseudo-science is more dangerous than no science at all.”). But see Randolph N. Jonakait, *The Meaning of Daubert and What That Means for Forensic Science*, 15 CARDOZO L. REV. 2103, 2103 (1993) (arguing that “[t]his can be done only if there are general standards and methods applicable to all fields of science that distinguish genuine science from pseudoscience”).

105. See Margaret A. Berger, *What Has A Decade of Daubert Wrought?*, 95 AM. J. PUB. HEALTH S59, S65 (2005) (“*Daubert* works effectively as another tool for terminating litigation without a trial or jury.”); Jeffrey S. Parker, *Daubert’s Debut: The Supreme Court, the Economics of Scientific Evidence, and the Adversarial System*, 4 SUP. CT. ECON. REV. 1, 5 (1995) (discussing *Daubert* and “minimizing the costs of litigation”).

106. See Parker, *supra* note 105 (discussing *Daubert* and “disciplining the content of scientific evidence”). The same justifications apply to the existence of the previous *Frye* standard, although the details of the test differ. See Edward K. Cheng & Albert H. Yoon, *Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards*, 91 VA. L. REV. 471, 475 (2005) (discussing adoption of *Daubert* and *Frye* standards in state court and noting “the choice between a *Frye* and *Daubert* standard does not make any practical difference”).

107. E.g., Elizabeth DeCoux, *The Admission of Unreliable Expert Witness Testimony Offered by the Prosecution: What’s Wrong with Daubert and How to Make it Right*, 2007 UTAH L. REV. 131 (2007) (discussing failures of *Daubert* in criminal proceedings); Jonakait, *supra* note 104, at 2103.

results, lowers the chance of delving into costly discovery, and disciplines pleading to focus on plausibility from the outset.<sup>108</sup>

The mechanisms for this analysis are not novel. The first is Rule 9, which requires fraud to be pled with particularity. The heart of most testing lawsuits is an allegation of fraudulent conduct, claims of fraud, fraudulent misrepresentation, and fraud-related consumer protection violations follow. According to Rule 9, fraudulent conduct must be pled in detail, or “with particularity.”<sup>109</sup> The rationale behind this rule is the risk of abusive litigation that often accompanies allegations of fraud—it is otherwise easy to plead but enormously damaging to defendants.

Courts have often interpreted this as requiring a plaintiff plead the “newspaper story” elements of the alleged fraud: who, what, where, when, and how.<sup>110</sup> While plaintiffs often allege details concerning the plaintiff’s purchase, such as the location of the seller, or how much the plaintiff paid, plaintiffs in testing suits generally do not provide details on the testing itself—the core factual matter that reveals the alleged fraud.<sup>111</sup> The defendant is thus left to respond to a lawsuit without knowing who performed the testing, what testing methods were used, or how much product was tested. In other words, defendants lack the very information they need “so that they can defend against the charge and not just deny that they have done anything wrong.”<sup>112</sup>

For example, in *Tye v. Walmart Stores, Inc.*, the plaintiff devoted no less than eight pages of the complaint to scans of his receipts for Pork & Beans, while devoting only three sentences to the testing that formed the meat of the complaint, such as noting it was “rigorous” and involved “microscopic and chemical analysis.”<sup>113</sup>

108. The general informational asymmetries in litigation have been the subject of much study. See, e.g. Corinne L. Giacobbe, *Allocating Discovery Costs in the Computer Age: Deciding Who Should Bear the Costs of Discovery of Electronically Stored Data*, 57 WASH & LEE L. REV. 257, 258-59 (2000) (discussing the \$3 million incurred by a defendant in response to a single discovery request and noting that electronic discovery has “a significant impact on the results of numerous cases”); Curt Cutting, *Turning Point for Rule 10b-5: Will Congressional Reforms Protect Small Corporations?*, 56 OHIO ST. L.J. 555, 560-61 (1995) (noting asymmetric discovery burdens in 10b-5 litigation).

109. FED. R. CIV. P. 9(b).

110. E.g., U.S. *ex rel.* Joshi v. St. Luke’s Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) (“To satisfy the particularity requirement of Rule 9(b), the complaint . . . must identify the ‘who, what, where, when, and how’ of the alleged fraud.” (quoting United States *ex rel.* Costner v. United States, 317 F.3d 883, 888 (8th Cir. 2003))); Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003) (internal quotations omitted) (requiring “the who, what, when, where, and how of the misconduct charged”); *In re* GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1547-48 (9th Cir. 1994) (internal quotation marks and modifications omitted) (superseded on other grounds) (requiring a plaintiff identify “[t]he time, place, and content of [the] alleged misrepresentation[s],” and “circumstances indicating falseness” or “manner in which the representations [at issue] were false and misleading”).

111. For example, in litigation over the nutrient quantity of multivitamins in *Dougherty*, the defendant producer argued that the product testing be pleaded with particularity. The plaintiff’s response reiterated the complaint by answering “How? By misrepresenting . . . the amount of . . . vitamins and minerals in the Multivitamin.” Plaintiff’s Response to Defendant’s Motion to Dismiss at 15, *Dougherty v. Source Naturals, Inc.*, No. 4:15-cv-00574-RLW (E.D. Mo. May 21, 2015). *But see* Kumar v. Salov N. Am. Corp., No. 14-CV-2411-YGR, 2015 U.S. Dist. LEXIS 12790, at \*16 (N.D. Cal. Feb. 3, 2015) (finding complaint sufficient to satisfy Rule 9 without actual test results, noting “[t]he level of detail Salov seeks is not necessary at the pleading stage”).

112. Swartz v. KPMG LLP, 476 F.3d 756, 764 (9th Cir. 2007).

113. Second Amended Complaint at 15, *Tye v. Walmart Stores, Inc.*, No. 8:15-CV-01615-DOC-JCG (C.D. Cal. May 20, 2016). In an effort to head off a preemption challenge, the plaintiff also alleged compliance with unspecified “FDA Protocols,” and that at least 12 “samples” were used in testing. *Id.* at 15.

This general lackadaisical attitude towards pleading testing results has costs: when a defendant is left in the dark concerning the key aspect of the plaintiff's complaint, there can be no meeting of the minds leading to settlement. Both sides of the litigation may value the strength of the claim at such different values that early (e.g. pre-discovery) resolution may be impossible.<sup>114</sup>

### C. *Twombly* and *Iqbal* in Testing Claims

Next, the plausibility standards embodied in *Twombly* and *Iqbal* should inform early evaluation of testing claims. A court must dismiss a complaint under Rule 12(b)(6) when it does not “contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.”<sup>115</sup> This “requires a plaintiff to show at the pleading stage that success on the merits is more than a ‘sheer possibility.’”<sup>116</sup> These cases characterized a shift in the philosophy of pleading. As put by Henry Noyes, prior pleading standards required that the court “accept the vision of the world described in the plaintiff's complaint,” while *Twombly* and *Iqbal* require that “courts . . . develop a common law of federal pleading standards that will be improved and refined over time.”<sup>117</sup>

While previously the plaintiff's factual allegations were accepted as true,<sup>118</sup> now “judicial experience and common sense” interpret the “factual matter” in the complaint and reach a conclusion on whether the plaintiff's claim is plausible.<sup>119</sup> The level of factual matter alleged in product testing claims varies widely, from chromatography output in *Gubala* to a single sentence in *Fonseca*.<sup>120</sup> However, courts have not quibbled over the level of detail.<sup>121</sup> For example, in *Fonseca* the court noted, “whether a product labeled as ‘Octopus’ contains squid instead of octopus is a question of fact, not a question of law, and asserting that DNA testing found that the Octopus Products contained squid is a plausible factual allegation.”<sup>122</sup>

Despite the difficulty defendants face evaluating a testing claim with little factual material, there are potential reasons behind the reluctance of courts to engage the machinery of *Twombly* and *Iqbal* in these claims. The actual test results may be

114. See STEVE SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 401-07 (2004) (modeling settlement as a function of party beliefs regarding the value of the case).

115. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted).

116. *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678).

117. Henry S. Noyes, *The Rise of the Common Law of Federal Pleading: Iqbal, Twombly, and the Application of Judicial Experience*, 56 VILL. L. REV. 857, 858-59 (2012).

118. *E.g.*, *Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993) (“We . . . must accept as true all the factual allegations in the complaint.”); *United States v. Shubert*, 348 U.S. 222, 225 (1955) (“The allegations . . . on a motion to dismiss, must of course be taken as true.”).

119. *Iqbal*, 556 U.S. at 678-79.

120. Complaint at 2, *Fonseca*, No. 5:16-cv-02559-HRL (“Independent DNA testing determined that Goya’s Octopus Products are actually jumbo squid and not octopus.”).

121. *See, e.g.*, *Tye v. Wal-Mart Stores, Inc.*, No. 8:15-CV-01615-DOC-JCG, slip op. at 8 (C.D. Cal. Apr. 26, 2016) (noting that the mere allegation that testing occurred, along with a photo of product, was sufficient to withstand Wal-Mart’s motion to dismiss).

122. *Fonseca v. Goya Foods Inc.*, No. 5:16-cv-02559-LHK, slip op. at 10 (N.D. Cal. Sept. 8, 2016). In accepting these allegations as plausible, the court did not define what allegations of testing would *not* be factually plausible.

informally shared between parties off the record, and thus inform settlement decisions without the court's input. Courts may simply be reluctant to engage in the factual inquiry necessary to engage a testing result for plausibility early in litigation, preferring instead to let the test results play out during discovery or trial.<sup>123</sup> Alternatively, courts may be presuming that plaintiffs will not make testing allegations that fall outside the boundaries of Rule 11.<sup>124</sup>

This is regrettable. Early pleading of test results aids the defendant, the plaintiff, and the court system. For defendants, early pleading of test results lowers litigation costs by allowing pre-discovery arguments, such as preemption, to be raised at more than the theoretical level. In other words, even if the factual matter in the complaint satisfies Rule 11 (e.g. testing actually occurred, and substantively supported the allegations in the complaint), testing often has subtle legal and practical implications that cannot be explored without results in hand. It is difficult to respond to allegations of a test with no details, and easier to respond the greater the level of specificity in the complaint.

Early pleading of test results may also aid the plaintiff. For example, in the *Gubala* litigation about the protein content of a dietary supplement, the plaintiff opted to attach the test results to the initial complaint. Although federal preemption was a possible issue (which would have held the testing inadequate), the court found the plaintiff's attached testing "nudge[d] his claims . . . 'across the line from conceivable to plausible.'"<sup>125</sup> When plaintiffs and defendants are aided through an information-expanding policy, courts are also helped through reduced docket loads and lesser need to shepherd litigants through discovery.<sup>126</sup>

#### D. "No-Injury Claims" and Practical Significance

If plausible and pled with particularity, initial analysis of testing claims should then be informed by the broad debate about statistical versus practical significance that touches every aspect of science.<sup>127</sup> This is most easily illustrated with the language of significance testing, but applies broadly to testing results whether or not they

123. The judiciary reflects the background of lawyers in general, who often come from backgrounds outside the hard sciences. See, e.g., Donna M. Gitter, *Should the United States Designate Specialist Patent Trial Judges? An Empirical Analysis of H.R. 628 in Light of the English Experience and the Work of Professor Moore*, 10 COLUM. SCI. & TECH. L. REV. 169, 172 (2009) (quoting William C. Rooklidge & Mansi H. Shah, *Creation of the Right to Interlocutory Appeal of Patent Claim Construction Rulings and Mandatory Stay Pending Appeal, The Coalition for 21st Century Patent Reform*, July 10, 2007, at 8, [http://www.patentsmatter.com/issue/pdfs/Interlocutory\\_Review\\_Paper.pdf](http://www.patentsmatter.com/issue/pdfs/Interlocutory_Review_Paper.pdf)) ("Many commentators attribute[d] the relatively high claim construction reversal rate to the fact that federal district court judges lack 'both technical training and frequent exposure to patent cases in general and patent claim construction issues in particular.'"); Michael Nieswiadomy, *LSAT Scores of Economics Majors: The 2008-2009 Class Update* at 5 (2009), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1430654](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1430654) (noting majors of 2008-2009 LSAT takers, with political science leading the pack by a wide margin).

124. Rule 11 requires that "factual contentions have evidentiary support or . . . will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." FED. R. CIV. P. 11.

125. *Gubala v. CVS Pharm., Inc.*, No. 14-c-9039, 2016 U.S. Dist. LEXIS 32759, at \*27 (N.D. Ill. Mar. 15, 2016). Whether the court would have accepted the allegations of testing without such support is unclear.

126. E.g., Godoy, *supra* note 10.

127. Compare, e.g., William E. Becker & William H. Greene, *Teaching Statistics and Econometrics to Undergraduates*, 15 J. ECON. PERSPECTIVES 169, 175 (2001) (noting "the considerable controversy in the economics profession as well as in the rest of the social sciences over the application of statistical significance versus the magnitude and practical

use the formal language of hypothesis testing. A test result is “statistically significant” when the sampling error is sufficiently low to show that the estimated value differs from the hypothesized value. In other words, a result is “significant” if the signal is sufficiently strong to differentiate it from the surrounding statistical noise. But since statistical significance is concerned only with sampling variability, it has little to do with the *practical* significance of the result.<sup>128</sup>

An example might be useful. Suppose a researcher wishes to examine a particular method for losing weight.<sup>129</sup> The researcher performs a large-scale study by randomly assigning many volunteers into a treatment group that follows the new methodology and a control group who does not. After observing these two groups over the course of several months, the research shows that members of the treatment group lost, on average, 1/100<sup>th</sup> of a pound more than members of the control group. The researcher also shows this result is statistically significant. What then?! A weight loss of that magnitude is unnoticeable compared to daily fluctuation in weight, has no practical bearing on health, and would hardly be cause for celebration. In other words, although statistically significant, the result has no practical significance.

This principle is often recognized in the law. In litigation over the amount of butterfat in croissants in *The Pillsbury Co. v. Upper Crust Production Co.*, the court considered whether test results showed a “material difference” from the 50% butterfat standard for butter blend croissants. The court accepted a material difference as one exceeding “7.5% on either end of the 50% butterfat requirement.”<sup>130</sup> Since test results were well outside that range, the court concluded the results to be practically significant.<sup>131</sup> Similarly, when examining potential discriminatory practices, the

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importance of an effect”); Deirdre N. McCloskey & Stephen T. Ziliak, *The Standard Error of Regressions*, 34 J. ECON. LIT. 97, 97 (1996) (“[O]ur main point . . . is that a difference can be permanent . . . without being ‘significant’ in other senses, such as for science or policy. And a difference can be significant for science or policy and yet be insignificant statistically, ignored by the less thoughtful researchers.”); Deirdre (né Donald) N. McCloskey, *Other Things Equal: The Bankruptcy of Statistical Significance*, 18 E. ECON. J. 359, 359-60 (1992) (gathering literature on critiques of statistical significance tests done without further consideration, such as to the power of the test); Deirdre (né Donald) N. McCloskey, *The Loss Function Has Been Mislaid: The Rhetoric of Significance Tests*, 75 AM. ECON. REV. 201, 201 (1985) (“[Significance] test[ing] can only affirm a likelihood of excessive skepticism in the face of errors arising from too small a sample. The test does *not* tell . . . whether a fitted coefficient is large or small in an economically significant sense.”) *with, e.g.*, Kevin D. Hoover & Mark V. Sieglar, *Sound and Fury: McCloskey and Significance Testing in Economics*, 15 J. ECON. METHODOLOGY 1, 4 (2008) (“We reiterate that we accept that statistical significance is not economic significance. No doubt there are cases of people mistaking one for the other. Yet, the evidence that this mistake is widespread and systematic is very weak.”); *id.* at 15 (“The principal claim – ‘the effect is empirically there, whatever the noise is’ – is extraordinary. Noise masks the signal. It may be there or it may not be there. The point is that we do not know.”).

128. In one sense, finding statistical significance is “easy.” There are established methods and well-studied principles that govern, and the outcome is usually pleasantly dichotomous (significant, or not). Practical significance is messy. There are no generally accepted guidelines for practical significance that span the sciences and no unifying language for the importance of practical effects across disciplines.

129. *E.g.*, performing Tabata reps timed to reading paragraphs of this Article.

130. *Pillsbury Co. v. Upper Crust Prod. Co.*, No. 98-cv-6114, 2004 U.S. Dist. LEXIS 307, at \*13 (W.D.N.Y. Jan. 6, 2004). The testing on buttered croissants represents a “golden” standard. Besides appropriately considering a margin of error, “[n]umerous tests performed by reputable independent laboratories following established scientific protocols produced consistent findings . . .” *Id.* The opinion is also an example of excellent legal writing. *E.g.*, *id.* at \*1, 36 (“The hard facts of this dispute center upon a soft roll known as the croissant . . . Exactly how much butter must a croissant blended with butter have to contain to be properly labeled a ‘butter blend’ croissant?”).

131. *Id.* at 36.

EEOC uses the “four-fifths” rule, in which the selection rate for a protected group is compared to the rate of the largest group of employees. A selection rate for the protected group less than four-fifths that of the largest group provides initial evidence of a discriminatory effect.<sup>132</sup> Even if the results of an analysis are statistically significant, the finding is potentially non-actionable unless the four-fifths rule is satisfied, that is, unless it meets the guidelines for practical significance.

In consumer class actions, one direct legal application of the practical significance principle is through the doctrine of standing.<sup>133</sup> Broadly speaking, the concept of standing enforces the constitutional requirement of an actual “case or controversy” before federal court jurisdiction exists.<sup>134</sup> It is evaluated according to the same plausibility standards as a motion to dismiss relying on *Twombly* and *Iqbal*.<sup>135</sup> As recently emphasized by the Supreme Court in *Spokeo, Inc. v. Robbins*, this requires an injury be both concrete and particularized.<sup>136</sup> An injury is particularized when it “affect[s] the plaintiff in a personal and individual way,”<sup>137</sup> and an injury is concrete when it “actually exist[s].”<sup>138</sup> As used in the context of the Fair Credit Reporting Act, an example of a non-concrete injury is “dissemination of an incorrect zip code” which, “without more, could not work any concrete harm.”<sup>139</sup>

Some types of testing results are analogous to the incorrectly reported zip code—if chemical test results show the presence of microscopic amounts of a foreign substance, undetectable to the consumer, and without any practical consequence, it might not *matter*. The results might not be practically significant. For example, consider the glyphosate litigation. In these cases, plaintiffs allegedly found 1.8 parts per

132. See Michael Stenger, *The First Circuit Strikes Out in Jones v. City of Boston: A Pitch for Practical Significance in Disparate Impact Cases*, 60 VILL. L. REV. 411, 413-14 (2015) (noting that some courts require practical significance in discrimination claims, while others do not). Compare, e.g., *Waisome v. Port Auth. of N.Y. & N.J.*, 948 F.2d 1370, 1376-77 (2d Cir. 1991) (noting “statistical significance does not show ‘importance’... or ‘practical significance’”) with, e.g., *Jones v. City of Boston*, 752 F.3d 38, 48 (1st Cir. 2014) (rejecting the argument that “even a showing of a statistically significant disparity is insufficient if the size of the impact is not sufficiently large, or ‘practically significant,’ as measured by the so-called four-fifths rule”); *Stagi v. AMTRAK*, 391 Fed. Appx. 133, 144-45 (3rd Cir. 2010) (“[T]his Court has never established ‘practical significance’ as an independent requirement for a plaintiff’s prima facie disparate impact case . . . [W]e find that in a case in which the statistical significance of some set of results is clear, there is no need to probe for additional ‘practical significance.’”). Of course, the parallel to employment law is inexact, because a *single* wrongful employment action would have practical impact on that person.

133. The state analog of standing in consumer class actions is the injury requirement embodied in state consumer protection laws. These vary by state, but often require an “ascertainable loss” or similar language. E.g., ALASKA STAT. § 45.50.531 (requiring “an ascertainable loss of money or property”); CONN. GEN. STAT. § 41-110g (requiring an “ascertainable loss of money or property”); FLA. STAT. § 501.211(2) (requiring a “loss”); LA. REV. STAT. ANN. § 51:1409 (“ascertainable loss”); MO. REV. STAT. § 407.025.1 (similar); N.J. STAT. ANN. § 56:8-1 (similar); ORE. REV. STAT. § 636.638(1) (similar); *White v. Mock*, 104 P.3d 356, 364 (Idaho 2004) (similar). Arguments similar to lack-of-standing can be raised under these laws, by alleging the consumer has not suffered actual loss, let alone one that is ascertainable.

134. E.g., *Baker v. Carr*, 369 U.S. 186, 204 (1962) (“Have the appellants alleged such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions? This is the gist of the question of standing.”).

135. E.g., *Hotchendonner v. Genzyme Corp.*, 823 F.3d 724, 731 (1st Cir. 2016) (collecting cases).

136. *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, slip op. at 1543 (2016).

137. *Id.* at 1548.

138. *Id.* (citing Black’s Law Dictionary 479 (9th ed. 2009)).

139. *Id.* at 1550.

million glyphosate in Quaker Oats products. This amount is far less than the level allowable by regulation, and has no reported effects on health or practical effect on the food as a preservative or otherwise.<sup>140</sup> In *Woods v. Nature's Variety*, the product in question was a pet food. The plaintiff alleged the presence of ethoxyquin in its pet food, an artificial preservative FDA allows in pet and human foods at certain levels.<sup>141</sup> The complaint did not allege testing the product, but posited the presence of ethoxyquin based on its possible use as a preservative of fish meal, which was an ingredient in the product. Alleging a trace preservative, that *might* have been used on an ingredient, was sufficient to reach a settlement, despite questionable practical significance.<sup>142</sup>

#### E. Preemption Possibilities

##### 1. Testing requirements for producers

A final aspect that courts and litigants should consider is whether claims will be preempted by federal law, such as by FDA regulation. Consumers take FDA labeling requirements as a fact of life, and learning to interpret nutrient content claims on FDA-mandated food labels is a rite of passage for functioning in modern society.<sup>143</sup> Less known are the requirements FDA has promulgated for calculating what goes on the label, and how FDA monitors compliance with labeling requirements. Under the Food Drug and Cosmetic Act of 1938 (the FDCA) and its revisions in the Nutrition Labeling and Education Act of 1990, FDA has promulgated various sets of rules governing product testing. There are two main divisions: rules for how a company decides what goes on a label, and rules for how FDA evaluates the label. While there is much product and ingredient-specific guidance regulation, the basic principles are straightforward.<sup>144</sup>

For food and supplement producers creating a label, FDA regulations do not provide detailed guidance on how to test nutrient claims. In its Food Labeling Guide, FDA notes it “has not stated how a company should determine the nutrient content of their product for labeling purposes . . . Regardless of its source, a company is

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140. *Cf. Gedalia v. Whole Foods Mkt. Servs., Inc.*, 53 F. Supp. 3d 943, 958 (S.D. Tex. 2014) (rejecting the argument that “since Whole Foods has developed a successful brand as a provider of natural foods, it should be obligated to guarantee every molecule in every product it sells under its in-house brand is natural”) (emphasis added).

141. *E.g.*, 21 C.F.R. §§ 172.140 (allowing up to 5 parts per million ethoxyquin in uncooked meat), 573.380 (allowing up to 150 parts per million ethoxyquin in animal feed).

142. By contrast, other test results show a clear potential for injury, such as when the quantity of goods sold differs from the labeled amount (under filled tuna), or where the quality of the good differs substantially from the labeled description (squid instead of octopus).

143. For example, many states include study of nutritional labeling as part of their public school curriculum. *E.g.*, Calif. Dept. Ed., *Nutrition to Grow On* (July 30, 2015), <http://www.cde.ca.gov/ls/nu/he/nrttogrow.asp>; Wisc. Dept. Pub. Instr., *Teaching Nutrition through Family and Consumer Sciences: A Curriculum Guide for Middle Schools* (2013), <https://dpi.wi.gov/sites/default/files/imce/school-nutrition/pdf/tncurr.pdf>; see also Dan J. Graham and Robert W. Jeffery, *Location, Location, Location: Eye-Tracking Evidence that Consumers Preferentially View Prominently Positioned Nutrition Information*, 111 J. AM. DIET ASSOC. 1704 (2011) (using eye-tracking software to analyze consumer use of nutrition labels and finding “[s]elf-reported viewing of Nutrition Facts label components was higher than objectively measured viewing”).

144. *E.g.*, 21 C.F.R. § 101.9(i) (outlining tests for protein content).



responsible for the accuracy and the compliance of the information presented on the label.”<sup>145</sup> For convenience, companies may rely on previously established food databases to compute nutrition values, and FDA provides an extensive guidance document on the development of such databases.<sup>146</sup>

## 2. Testing requirements for FDA enforcement actions

More precise rules apply when FDA evaluates a label claim. FDA monitors compliance with label statements according to the schema in 21 C.F.R. § 101.9(g). There are nine subsections. Sections (1) and (2) specify what FDA gathers to test a claim—a combined sample of twelve subsampled consumer units from twelve different shipping cases.<sup>147</sup> Section (2) further specifies that analysis must be conducted according to either FDA specifications or “the ‘Official Methods of Analysis of the AOAC International’” (the AOAC is a non-profit association that establishes chemical analysis methods).<sup>148</sup>

Subsections (3) to (9) detail what constitutes a violation, with differing requirements by nutrient.<sup>149</sup> These subsections also give guidelines for what is *not* a violation by specifically providing for the variability inherent in natural ingredients, manufacturing, and testing.<sup>150</sup> For example, subsection (4) notes that for “naturally occurring” nutrients, a test result at 80% or more of the labeled amount satisfies the regulation, and states that “no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.”<sup>151</sup> Subsection (5) furthers this concept, noting that deviations from labeled amounts are “acceptable within current good manufacturing practice.”<sup>152</sup>

145. FDA, *Guidance for Industry: A Food Labeling Guide* (Jan. 2013), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064894.htm>; see also FDA, *Guidance for Industry: Nutrition Labeling Manual - A Guide for Developing and Using Data Bases* (1998), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063113.htm#> (“The agency has not and does not intend to prescribe how an individual company is to determine nutrient content for labeling purposes.”).

146. See *id.* For some nutrients FDA provides additional guidance, such as by noting “[p]rotein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food. . . .” 21 C.F.R. § 101.9(c)(7). See *Durnford v. Musclepharm Corp.*, No. 15-cv-00413-HSG, 2015 U.S. Dist. LEXIS 170351 (N.D. Cal. Dec. 18, 2015) (discussing 21 C.F.R. § 101.9(c)(7)).

147. “The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot.” 21 C.F.R. § 101.9(g)(2). For dietary supplements the rules are slightly different. According to 21 C.F.R. § 101.36(f)(1), “the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot.”

148. 21 C.F.R. § 101.9(g)(2).

149. Nutrients are divided into two categories based on whether they are added to fortified foods or naturally occurring. Nutrients in fortified foods must test with at least the labeled amount, and naturally occurring nutrients must test at 80% of the label amount.

150. See *supra* Section III(A).

151. 21 C.F.R. § 101.9(g)(4).

152. Specifically, nutrient content may exceed the labeled amount consistent with good manufacturing practice, and calories, fat, cholesterol, and sodium may be deficient consistent with good manufacturing practice. *Id.*

### 3. Preemption as applied

Courts have approached preemption arguments in product testing claims in different ways. Some have embraced the doctrine at the motion to dismiss stage, while others have found allegations sufficient to continue into discovery. The policy justification for preemption based on the 12-sample methodology is simple. If not followed, courts implicitly require a higher standard for manufacturing quality control than that imposed by FDA. Ensuring that the mean level of a nutrient in a product meets FDA's 12-sample methodology is very different from ensuring the level of the nutrient in *each* product. Remember, variance is a function of sample size. The larger the sample size, the smaller the variance around the mean of a sample. Thus, ensuring quality control based on a 12-sample test is far easier than ensuring standards for each individual product.

The earliest case to find preemption based on the testing method did so at the summary judgment stage, in *Vital v. One World Co.*<sup>153</sup> There, the plaintiffs claimed One World mislabeled the amount of magnesium and sodium in its coconut water based on an independent test by ConsumerLab.com. The court granted summary judgment to the defendant because the testing did not comply with the 12-sample methodology in § 101.9(g)(2), and nicely summarized the statistical issues at play:

Under the § 101.9(g) methodology, it is impossible to determine whether a company is in compliance with the Food Labeling Rule by testing less than twelve products from twelve different shipping cases. If only eleven products are tested, a hypothetical twelfth product could raise the average nutrient content to a sufficient level.<sup>154</sup>

In following cases, preemption was found earlier than at summary judgment. In *Salazar v. Honest Tea, Inc.*, the plaintiffs claimed that “independent testing by a laboratory” showed the level of antioxidants in Honest Tea's Honey Green Tea did not match the label.<sup>155</sup> Again, because testing procedures did not follow the 12-sample methodology required by regulation, the court found the claim preempted by the FDCA on a motion to dismiss. Similar results have come in cases for a number of products, such as calorie count in ice cream,<sup>156</sup> the level of nutrients in vitamins,<sup>157</sup> the amount of protein in supplements,<sup>158</sup> and the amount of sugar in yogurt.<sup>159</sup>

Not all courts agree. Some have found the plaintiff's testing of a single purchase sufficient to overcome a motion to dismiss, reasoning that the test shows likelihood

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153. *Vital v. One World Co.*, No. SACV 12-00314-CJC (MLGx), 2012 U.S. Dist. LEXIS 186203, at \*15-16 (C.D. Cal. Nov. 30, 2013).

154. *Id.* at \*14.

155. *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313-14 (E.D. Cal. 2014). *See generally* James P. Muehlberger & Jeff Lingwall, *Plaintiffs Look Beyond Labels and Toward Product Testing*, LAW360 (2015) (discussing preemption and the *Honest Tea* case).

156. *Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 480-83 (D.N.J. 2013).

157. *Dougherty v. Source Naturals, Inc.*, 148 F. Supp. 3d 831 (E.D. Mo. Dec. 8, 2015).

158. *Bruaner v. MusclePharm Corp.*, No. 14-cv-8869-FMO(AGR), 2015 U.S. Dist. LEXIS 105515, at \*4 (C.D. Cal. Aug. 11, 2015); *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 U.S. Dist. LEXIS 63038, at \*11-12 (N.D. Cal. May 13, 2015).

159. *In re Whole Foods Mkt., Inc.*, No. A-14-MC-2588-SS, MDL NO. 2588, 163 F. Supp. 3d 385, 387 (W.D. Tex. Feb. 12, 2016).

that the 12-sample methodology would show similar results if performed.<sup>160</sup> For example, in *Gubala v. CVS Pharmacy*, the court found several factors significant. First, it relied on generous interpretation of *Twombly* and *Iqbal* from the Seventh Circuit to find that testing a single purchase made the complaint plausible. This puts much trust in a single data point. It also assumes the single data point will be predictive of the results from a larger, random sample, which may not be the case if, e.g., multiple purchases had been tested and an outlying result had been chosen to report.<sup>161</sup>

Next, the court cited FDA discussion noting that producers may verify label contents as they pleased, so long as the labels also complied with the methodology in § 101.9. The court then reasoned that “[i]f CVS can show regulatory compliance using other reliable methods, then it would make sense that [the plaintiff] should similarly be able to show non-compliance using other reliable methods.”<sup>162</sup> This reads the regulation and guidance backward, putting the cart (enforcement under § 101.9) ahead of the horse (internal quality control methods). Producers do not show regulatory compliance using “other reliable methods.” Instead, they may use those methods internally so long as those methods *lead to* products compliant under § 101.9.

## V. CONCLUSION

As testing methods continue to improve, publicity surrounding testing-based lawsuits spreads, and testing becomes increasingly affordable, litigation based on product testing will play an increasingly important role in consumer class actions. The particular litigation hooks may change over time, but the technique of embedding testing results as the foundation of class action complaints will remain. For instance, many of the cases discussed in this Article hinged on use of the word “natural” on the label, which the testing challenged based on the presence of unnatural substances. Because of the quantity of these lawsuits, many companies are moving away from use of “natural” on their labeling, and FDA is considering rules that would give regulatory meaning to the term.<sup>163</sup> But whether “natural” is replaced on labels by “essential,” “simple,” “real,” “honest,” or “ancient,” analogous litigation hooks will remain and testing-based litigation will continue.

As claims based on testing continue to proliferate, it becomes increasingly important for courts to apply sensible pleading standards and serve as gatekeepers to

160. *Gubala v. CVS Pharm., Inc.*, No. 14-c-9039, 2016 U.S. Dist. LEXIS 32759, at \*28 (N.D. Ill. Mar. 15, 2016) (“[T]his Court holds that Plaintiff may rely on the testing results attached to the amended complaint to nudge his claims based on an overstated declaration of protein content ‘across the line from conceivable to plausible.’”) (quoting *Twombly*, 550 U.S. at 570); *Smith v. Allmax Nutrition, Inc.*, No. 1:15-CV-00744-SAB, 2015 U.S. Dist. LEXIS 171897, 2015 WL 9434768, at \*7-8 (E.D. Cal. Dec. 24, 2015) (similar); *Clay v. Cytosport, Inc.*, No. 15-cv-165 L(DHB) (Aug. 19, 2015) (“Of course, in order to ultimately prevail on these claims, Plaintiffs will have to prove that Defendant did not comply with the FDCA provisions listed above. However, to state a claim, Plaintiffs only need to allege a plausible violation of the FDCA.”).

161. Due to natural variance in levels of nutrients in any product, sufficient seriatim testing would generally reveal *something* varying from the label. If enough clover leaves are picked at random, you will find one with four leaves, regardless of luck.

162. *Gubala*, 2016 U.S. Dist. LEXIS 32759, at \*29-30 (discussing Food Labeling; General Provisions; Nutrition Labeling; Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302-01, 2311, 1993 WL 1540 (F.R.) (Jan. 1993)).

163. *E.g.*, *Mortazavi*, *supra* note 2, at 945-50, 962-65; 80 F. R. 69905 (Nov. 12, 2015) (announcing notice and comment period for potential FDA regulation of the word “natural”).

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claims that fail to plausibly show injury. The tools and principles provided in this Article propose such a framework, showing how well-worn pleading requirements such as Rule 9(b), *Twombly* and *Iqbal*, traditional notions of standing, and awareness of preemption possibilities can shepherd testing lawsuits toward efficient resolution. As high but obtainable standards are applied to food *and* litigation, the promise of food forensics to effect meaningful change will be realized.