IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DOCTOR'S DATA, INC., a Nevada corporation,	)	
	)	No. 10-CV-3795
Plaintiff,	)	
v.	)	Hon. John J. Tharp, Judge Presiding
STEPHEN J. BARRETT, M.D., NATIONAL COUNCIL AGAINST HEALTHFRAUD, INC., a California, corporation, and QUACKWATCH, INC., a dissolved Pennsylvania corporation,	)	JURY DEMAND
Defendants.	)	

PLAINTIFF DOCTOR'S DATA'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT ON COUNT 5 AND DEFENDANTS' AFFIRMATIVE DEFENSES

Plaintiff Doctor's Data, Inc. ("DDI"), through its attorneys, respectfully moves this Court to enter summary judgment in its favor on its Count 5 (Libel *Per Se*) and Defendants' affirmative defenses of statute of limitations and latches. In support, DDI states as follows.

I. NATURE OF THE CASE

Since the 1970s, Defendant Stephen Barrett, a retired psychiatrist who failed his board certification exam, has been a self-anointed "consumer health advocate." (LR ¶ 7) He has launched numerous web sites from which he attacks medical philosophies not considered "mainstream", such as chiropractic, acupuncture, naturopathy, and integrative medical practices. (LR ¶ 8) In so doing, he professes to be an expert in how to attack his victims without being sued for libel.

he cautions. (LR ¶ 9)

Ironically, Dr. Barrett violated his own directive when he labeled Doctor's Data a "shady lab" engaging in a "fraud" and "scam" to "trick" its clients' patients, causing significant damage to Doctor's Data, a federally and state certified clinical laboratory.

Indeed, from 2009 through the present, the Barrett Defendants[1] have: (1) widely published false Internet statements about Doctor's Data, including but not limited to claiming that DDI is a "shady lab" that conspires with "nonstandard" physicians to "defraud" and "scam" patients into falsely believing that they suffer from "metal body burden," and (2) affirmatively encouraged third-party patients—for whom DDI merely processed urine specimens consistent with physicians' ordering instructions—to file baseless state-court lawsuits against DDI, among others. Readers of the libelous publications were encouraged to contact Barrett, who then referred them to an attorney, telling him, "[redacted]." (LR ¶ 10)

When the Barrett Defendants continued their tortious conduct unabated despite a request to cease and desist, DDI was compelled to file this lawsuit. At this stage in the proceedings, DDI's complaint consists of the following claims: (1) Lanham Act/Deceptive Practices (Count 1); (2) Trademark Dilution (Count 2); (3) Libel *Per Se* (Count 5); (4) Libel *Per Quod* (Count 6); (5) Tortious Interference (Count 7); (6) Civil Conspiracy (Count 9); and, corporate director liability (Count 10). (LR ¶ 11)

Although substantial evidence supports each of DDI's claims, summary disposition against the Barrett Defendants is particularly appropriate as to DDI's claim of libel *per se* in Count 5. For purposes of this motion, DDI identifies five false statements published by the Barrett Defendants that impute to DDI "fraud," "unfitness," "dishonesty," and/or "criminality" sufficient to prove libel *per se*. DDI satisfies herein all of the elements of libel *per se*, none of which can be disputed with genuine material facts.

With respect to the penultimate element of "falsity" – the only libel *per se* element possibly contested by Defendants – the undisputed facts establish that the Barrett Defendants'

[1] The phrase "Barrett Defendants" refers to all of the named defendants, Stephen J. Barrett, M.D., National Council Against Health Fraud, Inc. (NCAHF), and Quackwatch, Inc.

aforementioned five statements are demonstrably false. For instance, the federal laboratory licensing authority, known as "CLIA," has expressly addressed and rejected the Barrett Defendants' specific libelous claims that DDI's testing and reporting of provoked urine is a "fraud," "trick," or "scam" performed by a "shady lab." (LR ¶ 36) Similarly, the only court to directly address the Barrett Defendants' assertions has rejected them, finding that DDI's test report for provoked urine samples is not a "fraud," "misleading," or "deceptive." (LR ¶ 38-40) Furthermore, DDI presents ***unrebutted*** expert testimony that the Barrett Defendants' libelous statements against DDI are false based on, *inter alia*, accepted clinical laboratory standards and practice. Finally, the Barrett Defendants' libelous statements are demonstrably false because they rest on a fundamentally erroneous premise that DDI is *wrongly* including reference ranges in its results report for provoked urine samples, when, in fact, it is required as a matter of federal clinical laboratory regulatory standards. (LR ¶ 29-32)

Finally, summary judgment also is proper against the Barrett Defendants' two affirmative defenses of statute of limitations and laches. Indeed, these affirmative defenses are frivolous. Aside from having no factual evidence that would support either affirmative defense, the Barrett Defendants have affirmatively published and republished their libelous statements shortly before, and since, DDI's filing, rendering both affirmative defenses meritless.

II. FACTS

A. Barrett Defendants' *Per Se* Libelous Publications Against DDI.

In an effort to streamline its motion, DDI moves for summary judgment on some of the more prominent of the Barrett Defendants' *per se* libelous statements, all of which appear in at least one of the exhibits referenced in DDI's complaint:[2]

- "How the 'Urine Toxic Metals Test' is Used to Defraud Patients";
- DDI's "provoked [urine] testing is a scam";
- DDI's provoked "urine test is used to defraud [or "trick"] patients";
- DDI's "provoked urine toxic metals test is a fraud";
- DDI is a "[s]hady...lab" for its involvement in accepting and reporting on provoked urine samples. (LR ¶ 12)

To provide some brief context for the foregoing, DDI highlights the Barrett Defendants' still-widely disseminated and authored article, "*How the 'Urine Toxic Metals' Test Is Used to Defraud Patients.*" (LR ¶ 13) This publication expressly references "Doctor's Data" by name, calling it "a Chicago-based laboratory that caters to nonstandard practitioners," and reproduces a DDI test results report for a provoked urine sample. *Id.* In so doing, the Barrett Defendants falsely – and thus, libelously – claim that the provoked "urine test is used to defraud patients" and is a "scam" because DDI's "report classifies the man's lead and mercury levels as "elevated" because they are twice as high as the upper limit of their "reference ranges," which is "misleading" because the "reference range is based on non-provoked tests." *Id.*

B. Understanding DDI's Clinical Laboratory Operations Belies Defendants' Libel.

To properly evaluate the Barrett Defendants' libelous statements, some understanding of DDI's clinical laboratory operations is necessary, particularly as it relates to accepting and

[2] In the course of answering Defendants' interrogatories and supplemental interrogatories, DDI's attorneys identified some 85 statements which were libel *per se* or libel *per quod.* Much of the list is repetitious because Barrett repeatedly includes hyperlinks to his original articles. In December 2013, in an effort to make DDI's case more manageable and streamlined, DDI pared down the list of libelous statements to about 40.

reporting on "provoked urine" samples. DDI is a clinical laboratory that analyzes urine, fecal, and blood specimens submitted by clinicians for testing for their patients. (LR ¶ 19) Like many clinical laboratories, Doctor's Data offers tests to analyze urine specimens. Urine is often tested to assess, among other things, the level of "metals" (sometimes referred to as "toxic metals"), such as mercury or lead, within the urine sample. (LR ¶ 20)

Physicians submit a urine sample to DDI which is either "unprovoked" or "provoked". "Unprovoked urine" is urine as it would typically occur in the patient's daily life. On the other hand, "provoked urine" involves the physician first administering a "chelating agent" to the patient prior to the collection of the urine sample. The "chelating agent" draws out metals from the body.

Some physicians (not all) believe that laboratory testing of a "provoked urine sample" can be helpful in either of two contexts. (LR ¶ 22) First, they may submit to DDI a provoked urine sample and compare it to an unprovoked urine sample, to assist in differentiating between near term exposure to metals and the longer term accumulation of metals in the body, sometimes referred to as "metal body burden." *Id.* Second, if "metal body burden" is clinically suspected, some physicians (not all) may recommend a course of "chelation treatment," whereby "chelating agents" are periodically provided to the patient with the goal of drawing metals and eliminating them from the patient's body in urine. (LR ¶ 23) Under this second scenario, these physicians will periodically submit to DDI (or some other laboratory) provoked urine samples so they can compare the patient's prior provoked urine results to determine if metal content is declining over time with the chelation treatments. (LR ¶ 24)

While reasonably well qualified physicians may disagree on the medical efficacy of chelation treatments and testing provoked urine, there can be no genuine dispute as to DDI's role. DDI is a clinical laboratory. (LR ¶ 25) DDI does not practice medicine. *Id.* DDI does not see patients. *Id.* DDI does not clinically assess patient symptoms or conditions. *Id.* DDI does

not decide whether physicians should submit provoked or unprovoked urine specimens. *Id.* DDI does not clinically interpret the results of a patient's provoked urine sample. *Id.* DDI does not diagnose illness. *Id.* DDI does not order any type of patient treatment, be it chelation or any other type. *Id.* Finally, DDI does not control how its test results are interpreted or understood by an ordering physician. *Id.* DDI is strictly a clinical laboratory that analyzes specimens and reports its findings to the physician who ordered the test. *Id.*

Many times, an ordering physician will not even inform DDI whether a urine sample is "provoked" or "unprovoked." (LR ¶ 26) DDI does not need to know this information. *Id.* As with other clinical laboratories, irrespective of whether the received urine sample is "provoked" or "unprovoked," DDI performs the same testing protocol and issues the results on the same test results report form. (LR ¶ 27)

DDI's test results report is subject to federal law and standards. For instance, federal law requires DDI to identify a reference range on its test results report. (LR ¶ 28) A "reference range" allows the ordering physician to assess how her or his patient's urine test results compare to the urine results of a "typical" population. (LR ¶ 29) However, because there is no scientifically established "reference range" for *provoked* urine, DDI identifies the "reference range" applicable to unprovoked urine (as it is required to do under federal law) and then includes qualifying language—in bold lettering—stating that the reference range is inapplicable if the test was of a provoked urine specimen. (LR ¶ 30) Doing so is an acceptable, indeed mandated, industry practice. (LR ¶ 31)

An exemplar of DDI's urine test results report (again, used for both provoked and unprovoked urine specimens) is attached as Exhibit 4. However, below is a basic reproduction:

Metals	Result	Ref. Range	W/in RR	Elevated	V. Elevated
Lead	10	<5	---------->		
Mercury	6.5	<3	---------->		

> **Reference ranges are representative of a healthy population under non-challenged or non-provoked conditions.** No safe reference levels for toxic metals have been established.

(LR ¶ 33) DDI's report statement advising, **"Reference ranges are representative of a healthy population under non-challenged or non-provoked conditions**" is hereinafter referred to as DDI's "Qualifying Language."

C. CLIA And At Least One Court Have Rejected Defendants' Libelous Claims.

The Barrett Defendants persist—even to this day—in libeling DDI, even though they know that federal regulating authorities and one court expressly reject their libelous claims that DDI is a "shady lab" engaging in "fraud" or "misleading" laboratory practices. Indeed, the Barrett Defendants repeatedly requested CLIA officials to investigate, audit, and punish DDI for its alleged "fraudulent," "misleading," and "deceptive" practices relating to provoked urine testing and reporting. (LR ¶ 35)

"CLIA" stands for the The Clinical Laboratory Improvement Amendments. (LR ¶ 34) It is the vehicle by which the Center for Medicare and Medicaid Services ("CMS") regulates laboratory testing of human specimens. *Id.* Congress charged CMS with establishing CLIA standards for quality assurance and quality control that must be met by all U.S. clinical laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. *Id.*

The Barrett Defendants repeatedly emailed CLIA officials, lodging their complaints, presenting their so-called "proof," and insisting on remedial action, such as:

> I remain puzzled that your agency appears unwilling to ***stop the fraud*** involved in the way [Doctor's Data's provoked urine] ***tests are reported.*** How can you let them get away with ***using a false reference range to interpret their reports***?
> LR ¶ 35) (Emphasis Added)

Yet, CLIA officials rejected the Barrett Defendants' claims of fraudulent reporting against Doctor's Data, ***every time***. For instance, in July 2010, CLIA circulated an internal email:

> ***I found no real problems with this lab. The urine metal reference ranges are reflective of the published CDC ranges***. Validation studies were performed on all of the analytes that I have reviewed. QC and PT are being performed with no real problems. ***I honestly do not see a problem with the testing***.

(LR ¶ 36) (Emphasis Added) Similarly, in another internal email, a CLIA official acknowledged, "I have inspected this lab at various times due to [the Barrett Defendants'] ***constant complaints. We have only been able to cite standard level or no deficiencies at this lab with each onsite inspection.***" *Id.* (Emphasis Added) CLIA's ongoing certification after "each onsite inspection" in the wake of Barrett Defendants' "constant complaints" is significant, if not dispositive, as to the falsity of the Barrett Defendants' libelous claims.

Like CLIA, the only court to have directly addressed these issues also rejected the Barrett Defendants' claims that Doctor's Data is engaging in misleading, shady, fraudulent, and/or deceptive practices. *Pfister v. Medical Wellness Institute, Doctor's Data, and Vinu Patel, M.D.*, No. 49D10-0802-CT-005046 (Marion County, Indiana). (LR ¶ 38) Indeed, the *Pfister* court granted DDI summary judgment. In so doing, the *Pfister* court expressly rejected the truth of Barrett Defendants' specific claims. (LR ¶ 39-40) In particular, the *Pfister* court held that DDI provided "an explanation of the provided reference range . . . in bold lettering and in sufficiently clear terms for *Pfister* [the patient] himself to question the application of the reference range" to his provoked urine specimen. (LR ¶ 39) By finding DDI's Qualifying Language on its results report for provoked urine samples sufficiently clear, the *Pfister* court rejected the notion that DDI's reporting was a "fraud," a "scam," "deceptive," or "misleading."

In addition to so holding, the *Pfister* court also emphasized that DDI was entitled to rely on the ordering physician to understand and explain the significance, if any, of DDI's findings identified in its test results report. Specifically, the *Pfister* court concluded:

> Doctor's Data did not owe Pfister [the patient] a duty of care to interpret the results of his [provoked] urine test. The level of interaction between Doctor's Data and Pfister is too minimal to impose such a duty. Doctor's Data did not order the urine test, determine how the urine should be collected, or determine whether Pfister should be injected with a provoking agent prior to the urine test. Further, Doctor's Data did not examine Pfister or have any information regarding the context in which the urine test was ordered. Doctor's Data was not involved in making this diagnosis or in recommending any treatment. Instead, Doctor's Data provided the Report to Pfister's physicians who are qualified to interpret the results and offer a diagnosis. Doctor's Data's role was limited to testing Pfister's urine sample and reporting the results. Doctor's Data did not owe a duty of care to interpret those results. (LR ¶ 64)

Notwithstanding the foregoing pronouncements by CLIA and the *Pfister* court, the Barrett Defendants choose to continue making their false statements that DDI's acceptance of, and reporting for, provoked urine specimens is "shady," "fraudulent," "misleading," a "scam," and "deceptive."

D. DDI's Experts Confirm DDI's Practices Are Proper And Defendants' Claims Are False.

DDI's experts confirm the foregoing conclusions of CLIA and the *Pfister* court relating to the propriety of DDI's practice of accepting and reporting on provoked urine samples submitted to it by clinicians. DDI has disclosed three "liability" expert witnesses, two of whom with vast experience in operating CLIA-certified clinical laboratories. For instance, Dr. Russell Jaffe is an M.D./Ph.D. from Boston University, board certified by the National Board of Medical Examiners and the American Board of Pathology for Clinical and Chemical Pathology, and is both a clinician and lab director. (LR ¶ 41) Dr. Jaffe observes:

> The fact that at all times at issue in this case Doctor's Data has been and still is a fully accredited, inspected, and licensed clinical laboratory certified by CAP, CLIA, and the New York Department of Health, all three having standards which are rigorously enforced, affirms that Doctor's Data is a properly regulated and inspected clinical laboratory engaging in no wrongdoing, notwithstanding

> Defendants' specific accusations about "fraudulent," "shady," or "misleading" practices. (LR ¶ 37)[3]

Dr. Jaffe's more specific expert opinions, too, are significant in demonstrating the falsity of the Barrett Defendants' claims. For instance, Dr. Jaffe notes that DDI's practice of accepting, analyzing, and reporting on provoked urine specimens (just like many other clinical laboratories throughout the country) is "consistent with industry standards and good laboratory practices." (LR ¶ 42) Even more specifically, Dr. Jaffe explains that DDI's "report format" for reporting the results of a provoked urine sample, including its inclusion of reference ranges and graphing applicable only to non-provoked urine samples, is "consistent with industry standards and practices and is neither 'misleading' nor 'uninterpretable'." (LR ¶ 43)

Dr. Jaffe's views are echoed by Gregory Clark, a Ph.D. in analytical chemistry from the University of Washington, the director of a CLIA-certified laboratory, a fellow in the Academy of Clinical Biochemstry, and a diplomate in the American Board of Clinical Chemistry. (LR ¶ 44) Like Dr. Jaffe, Dr. Clark opines that the Barrett Defendants "incorrectly label" DDI as a "shady" laboratory for accepting, processing, and reporting on provoked urine samples. (LR ¶ 45) In so concluding, Dr. Clark emphasizes: (1) CLIA's rejection of the Barrett Defendants' specific complaints, (2) CLIA's on-going certification of DDI, among other independent certifying agencies, including all those states which require independent certification, namely, New York, Florida, Pennsylvania, Rhode Island, and California, and (3) DDI's practices with respect to provoked urine testing and reporting are "consistent with industry standards and practices." *Id.*

DDI's third "liability" expert, Dr. Robin Bernhoft, concurs. Dr. Bernhoft's expertise is more directed toward the medical/clinician aspects of this case, as opposed to clinical laboratory aspects. Dr. Bernhoft is a graduate of Harvard and Washington University School of Medicine,

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[3] CAP is an acronym for the College of American Pathologists.

is certified by the American Board of Surgery and the American Board of Environmental Medicine, is a practicing physician, and is well published in the field of heavy metal body burden. (LR ¶ 46)

With respect to the medical aspects of this case, Dr. Bernhoft explains that "metal body burden is an adverse medical condition that can cause a host of symptoms, often serious and debilitating, and that analysis of provoked urine specimens is an important, necessary adjunct to treatments designed to excrete these metals and restore the patient to good health." (LR ¶ 47) Dr. Bernhoft notes that "*unprovoked* urine, blood, and hair samples correlate with *recent* heavy metal intake but *not* body burden." (LR ¶ 48) (Emphasis Added) "Certainly," Dr. Bernhoft writes, "heavy metal body burden is a real and recognized phenomenon as a matter of toxicological science. Moreover, chelation is a recognized therapy to remove stores of heavy metal toxins found within the body, which is identifiable by a trained and qualified physician through *clinical evaluation and the urine toxic metals test.*" *Id.* (emphasis added)

Based on his training, experience, research, and knowledge, Dr. Bernhoft opines that the Barrett Defendants' "pejorative characterizations of Doctor's Data, its physician customers, and their respective practices" as alternatively, "offbeat," "cuckoo," "shady," "misleading," or "frauds" are "erroneous and untrue." (LR ¶ 49) Dr. Jaffe concurs, explaining:

> [B]ased on my training, experience, and knowledge, reasonable health care practitioners may differ on the meaning of heavy metal body burden and the use of various chelation therapies to treat this condition, but casting all of those who advocate or engage in this type of medical practice as "fraudsters" or "substandard" or some other name (*e.g.*, "cuckoos") is misguided, wrong, and bad for patient care and medical practice. . . . [G]rowing numbers of practitioners believe it is also important to know what is in the patient's tissues and cells, and have learned that provoked urine specimens provide such information more effectively than blood or unprovoked urine in some circumstances. (LR ¶ 50)

E. <u>The Barrett Defendants' Liability Expert, Dr. Ruha, Is Not A Clinical Laboratory Expert</u>.

The Barrett Defendants identified only one "liability" expert, whose expertise is limited to certain medical/clinician aspects of this case, not the clinical laboratory aspects of this case. The Barrett Defendants' sole "liability" expert is Dr. Anne-Michelle Ruha who specializes in researching, teaching, and treating victims of venom poisoning (as in snakes and spiders). (LR ¶ 51) Dr. Ruha, by her own admission, knows virtually nothing about clinical laboratory science, standards, and practice, so is in no position to expertly opine on the truth or falsity of the Barrett Defendants' attacks on DDI's clinical laboratory practices. (LR ¶ 52) For instance, in her deposition, Dr. Ruha conceded she is ***not "an expert*** in the field of regulations that would be ***applicable to clinical laboratories***.... [she] is ***not an expert in clinical lab report forms... I have no expertise about labs***." *Id.* (emphasis added)

Dr. Ruha's disclosed opinions in this case can be segregated into two categories. The vast majority of her opinions focus exclusively on the medical/clinician aspects of this case and are taken straight from her article, "*Recommendations for Provoked Challenge Urine Testing*" ("*Recommendations* Article"). In her *Recommendations* Article, Dr. Ruha criticizes as medically unsound metal body burden, provoked urine testing, and chelation treatment. (LR ¶ 54) Dr. Ruha published this article *before she ever knew about this case* and without reviewing any case materials. *Id.* Indeed, Dr. Ruha admits that aside from reviewing a handful of Doctor's Data's test results report forms and associated DDI "commentaries", she reviewed no pleadings, no depositions, no expert disclosures, and no other discovery related to this case prior to proffering any of her opinions in this case. (LR ¶ 55)

Dr. Ruha's other disclosed opinions, representing a very small percentage of the total, address the clinical laboratory aspects of this case, and she included them in a one-page attachment ("Attachment Opinions"). (LR ¶ 56) Based on her own admission of not being an expert (or having any knowledge or experience) in clinical laboratory practices, standards, and reports, DDI has

moved to bar these opinions under *Daubert* and FRE 702. *See* DDI's *Daubert* Motion (filed contemporaneously with this summary judgment motion). Nevertheless, to the extent applicable to this motion for summary judgment, Dr. Ruha's Attachment Opinions will be addressed below in DDI's "Legal Argument" section.

In short, Dr. Ruha's Attachment Opinions—those relating to clinical laboratory matters—can be summarized as follows. She opines, based on her limited experience with "dozens" of individuals, that DDI's test results report for provoked urine samples can be misleading to some individuals. (LR ¶ 57) However, in so stating, Dr. Ruha concedes that many other individuals will not be misled because they will understand DDI's test results report, as she does. (LR ¶ 58) (DDI's test result report for provoked urine sample "[c]ould be misleading to some but not to others," is only "potentially misleading," and is not misleading to her because she understands its disclaimer).

III. SUMMARY JUDGMENT STANDARD

Summary Judgment is appropriate when no genuine issue of material fact remains to be decided by the trier of fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Disputed facts are only material when they might affect the outcome of the litigation. *First Ind. Bank v. Banker*, 957 F.2d 506, 508 (7th Cir. 1992). As will be demonstrated below, there is no genuinely disputed material fact relating to the Barrett Defendants' *per se* libelous statements identified above, including those that DDI is a "shady" lab conspiring with "non-standard physicians" to "[de]fraud," "mislead," and "deceive" individuals. In addition, the Barrett Defendants' two affirmative defenses of statute of limitations and laches also must fail as a matter of law.

IV. LEGAL ARGUMENT

As explained below, this Court should grant DDI summary judgment on its Count 5 (Libel *Per Se*) and the Barrett Defendants' two affirmative defenses of statute of limitations and latches.

A. DDI Is Entitled To Summary Judgment On Count 5 (*Per Se* Libel)

DDI is entitled to summary judgment on Count 5, which is its libel *per se* claim against the Barrett Defendants. Per Judge Chang's prior ruling in this matter, Illinois libel law and North Carolina defenses to libel apply to this case. (Order, 11/22/11) [#82] The elements of libel *per se* are: (1) a written statement by the defendant; (2) published or communicated to someone other than the victim; (3) that either imputes to plaintiff criminal conduct, infection with a communicable disease, inability or incapability to perform one's profession, or unfitness to perform, or dishonesty in performing, one's duties of office or employment; and (4) which is false. *Bryson v. News American Publication*, 174 Ill. 2d 77, 88, 672 N.E.2d 1207, 1214-15 (1996); *Kolegas v. Heftel Broadcasting Corp.*, 154 Ill. 2d 1, 10, 607 N.E.2d 201, 207 (1992). If the court finds as a matter of law that a statement is libel *per se*, the victim will be presumed to have suffered injury and damages. *Id.*

There can be no genuine dispute that DDI has proven each of the foregoing four elements for the Barrett Defendants' five libelous statements identified herein. Again, they are:

(1) "How the 'Urine Toxic Metals Test' is Used to Defraud Patients";
(2) DDI's "provoked [urine] testing is a scam";
(3) DDI's provoked "urine test is used to defraud [or "trick"] patients";
(4) DDI's "provoked urine toxic metals test is a fraud"; and
(5) DDI is a "[s]hady…lab" for its involvement in accepting and reporting on provoked urine samples. (LR ¶ 12)

Here, DDI has indisputably proven the first two libel *per se* elements above, namely, "defendant's writing" and "publication." Statement 1, *"How the 'Urine Toxic Metals Test' is Used to Defraud Patients,"* is the title of an article by Defendant Barrett and published by Defendant Quackwatch on its website. (LR ¶ 14) Statement 2, the phrase that *DDI's "provoked [urine] testing is a scam"* is published within this same Barrett/Quackwatch publication. (LR ¶ 15) The same is true for Statement 3, that *DDI's provoked "urine test is used to defraud [or "trick"] patients."* (LR ¶ 16) The iteration using the phrase *"trick people"* (instead of "defraud patients") is from a published article by Defendant National Council Against Health Fraud, "edited by [Defendant] Stephen Barrett, M.D. and cosponsored by [Defendant] NCAHF and [Defendant] Quackwatch." (LR ¶ 16)

Statement 4, that *DDI's "provoked urine toxic metals test is a fraud"* also is from a published article by Defendant National Council Against Health Fraud, "edited by [Defendant] Stephen Barrett, M.D. and cosponsored by [Defendant] NCAHF and [Defendant] Quackwatch." (LR ¶ 17) The same is true for Statement 5, that *DDI is a "shady . . . lab"* for accepting and reporting on provoked urine samples. (LR ¶ 18)

Indeed, with respect to this second libel *per se* element of "publication," Defendant Barrett himself acknowledged the widely disseminated publication of the foregoing (and other) libelous statements. For instance,

" (LR ¶ 59) Similarly,

(LR ¶ 60) Accordingly, based on the foregoing, there

can be no genuine dispute that DDI has satisfied both the first element for libel *per se* (defendant's statement) and the second element (publication).

There also can be no genuine factual dispute that DDI has proven the third element of libel *per se*, namely: The statements impute to DDI an inherently injurious trait. The Barrett Defendants' foregoing five statements clearly do so because they impute "unfitness of one's duties," "dishonesty of one's duties," "fraud," "mismanagement," and/or "criminal conduct." *E.g., Audition Division, Ltd. v. BBB of Metropolitan Chicago, Inc.*, 120 Ill.App.3d 254, 256, 458 N.E.2d 115, 118 (1st Dist. 1983) (where the plaintiff is a corporation, business libel *per se* can be words which "assail the corporation's financial or business methods or accuse it of fraud or mismanagement"); *Bryson*, 174 Ill. 2d at 88, 672 N.E.2d at 1214-15 (*per se* liable exists if statements impute to plaintiff "inability or incapability to perform one's profession" or "unfitness or dishonesty of one's duties of office"). In particular, the foregoing terms—including *"defraud"* (Statement 1), *"scam"* (Statement 2), *"defraud"* or *"trick"* (Statement 3), *"fraud"* (Statement 4), and *"shady lab"* (Statement 5) – all impute "unfitness," "dishonesty," "fraud," "mismanagement," and/or even "criminal conduct."

Moreover, there can be no serious contention that the foregoing five statements impute these *per se* injurious traits to Doctor's Data. The Barrett Defendants' published statements prominently reference and castigate DDI by name. (LR ¶ 13); *Audition Division*, 120 Ill.App.3d at 256, 458 N.E.2d at 118 (holding that "the reports must be read in their entirety . . . , the meaning taken not only from the words but also from the context of the statement"). Indeed, when read in context, Defendant Barrett's article, *"How the 'Urine Toxic Metals Test' is Used to Defraud Patients,"* (which accounts for three of the five libelous statements), not only references DDI by name repeatedly but also reproduces DDI's test report for a provoked urine sample, specifically claiming that DDI's "report . . . is misleading." *Id.* Under these

circumstances, there can be no serious debate that each of the Barrett Defendants' five statements impute to DDI the injurious traits of "dishonesty," "fraud," "unfitness," and/or "criminality."

Even if the Barrett Defendants' actual words and context were insufficient to indisputably prove this third element (they are not), their injurious meaning and indictment of DDI are put to rest by Defendant Barrett's own emails. For example,

(LR ¶ 62) Accordingly, based on the clear text and context of Defendant Barrett's Internet publications and how they were understood by the public, there can be no genuine dispute that DDI has satisfied the third element for libel *per se*.

Finally, there is no genuine issue of material fact relating to the final element of libel *per se*, namely: that the foregoing five libelous statements are demonstrably "false." Once again, in summary form, the Barrett Defendants' five libelous publications claim the following as to DDI's test results report for provoked urine samples: (1) *"defraud"* (Statement 1), (2) *"scam"* (Statement 2), (3) *"defraud"* or *"trick"* (Statement 3), (4) *"fraud"* (Statement 4), and (5) *"shady lab"* (Statement 5). The foregoing five statements are demonstrably false for numerous reasons.

First, CLIA's rejection of these precise claims proves the falsity of the Barrett Defendants' statements. Specifically, Defendant Barrett complained to CLIA to "***stop the fraud*** involved in the way [Doctor's Data's provoked urine] ***tests are reported,***" specifically, as it relates to "***using a false reference range*** to interpret their [provoked urine test] reports." (LR ¶ 35) (emphasis added) Notwithstanding Defendant Barrett's "constant complaints" to these

federal authorities, CLIA officials rejected Defendant Barrett's claims of "fraud" and "false reference ranges," ***every time***. For instance, in July 2010, CLIA circulated an internal email, stating, "I found no real problems with this lab," and "I honestly do not see a problem with the testing." (LR ¶ 36) Similarly, another CLIA official noted in an email that "each onsite inspection" in response to Defendant Barrett's "constant complaints" revealed no substantive violations or deficiencies. *Id.* The foregoing undisputed facts alone prove the falsity of the Barrett Defendants' five published statements that DDI's testing and reporting of provoked urine specimens is a "fraud," "trick," or "scam" performed by a "shady lab."

Second, the court's decision in *Pfister* further establishes the falsity of the Barrett Defendants' claims that DDI's role in accepting and reporting on provoked urine specimens is a "fraud," "trick," "shady," or "scam." Defendant Barrett fomented the *Pfister* lawsuit, so the *Pfister* plaintiff's legal claims against DDI paralleled the Barrett Defendants' Internet statements against DDI. *Pfister v. Medical Wellness Institute , Doctor's Data, and Vinu Patel, M.D.,* No. 49D10-0802-CT-005046 (Marion County, Indiana). (LR ¶ 38-40) In October 2012, the Hon. David J. Dreyer of the Superior Court of Marion County, Indiana, granted DDI summary judgment, finding:

> The designated evidence shows that Doctor's Data ***did not make a misrepresentation of fact*** to Plaintiff Rick Pfister ("Pfister"). The Urine Toxic Metals and Urine Toxics Report (the "Report") contained the results of Pfister's urine test and a reference range. Pfister does not allege that the results of his urine test were false or otherwise fraudulent. None of the facts stated in the Report are untrue. Plaintiff's argument that Doctor's Data ***used an inapplicable, inappropriate, and/or scientifically invalid reference range and methodology***, even if proven true, ***do not constitute any knowing misrepresentation*** of fact as required to support a claim of actual fraud. Furthermore, ***an explanation of the provided reference range was stated, in bold lettering and in sufficiently clear terms for Pfister himself to question the application of the reference range***. As a result, there is ***no misrepresentation of material fact for fraud***. (LR ¶ 63)

The foregoing *Pfister* court's ruling was premised, in part, on the proper understanding of DDI's limited role with respect to provoked urine specimens, which belies any claim of "fraud"

or "scam" or "trick". The *Pfister* court recognized that DDI is a clinical laboratory (not a physician), and therefore DDI merely accepts, analyzes, and reports the results of urine samples received, an entirely legal and proper exercise (as confirmed by CLIA, numerous state licensing agencies, and DDI's experts). Even the Barrett Defendants' expert, Dr. Ruha, agrees by acknowledging, "[I]t is unlikely a lab is going to reject a sample because a provoking agent has been given." (LR ¶ 65) In particular, the *Pfister* court properly noted:

> Doctor's Data ***did not owe Pfister [the patient] a duty of care to interpret the results*** of his [provoked] urine test. The ***level of interaction between Doctor's Data and Pfister is too minimal*** to impose such a duty. Doctor's Data ***did not order the urine test, determine how the urine should be collected, or determine whether Pfister should be injected*** with a provoking agent prior to the urine test. Further, ***Doctor's Data did not examine Pfister or have any information regarding the context in which the urine test was ordered.*** Doctor's Data was ***not involved in making this diagnosis or in recommending any treatment.*** Instead, ***Doctor's Data provided the Report to Pfister's physicians who are qualified to interpret the results and offer a diagnosis***. Doctor's Data's ***role was limited to testing Pfister's urine sample and reporting the results***. Doctor's Data did not owe a duty of care to interpret those results. (LR ¶ 40) (Emphasis Added)

Accordingly, the falsity of the Barrett Defendants' five published Internet statements also is further established by the *Pfister* court's ruling and rationale.

Third, DDI's unrebutted expert disclosures also prove the falsity of the Barrett Defendants' five published statements that DDI's testing and reporting of provoked urine was a "fraud," "trick," or "scam" performed by a "shady lab." In particular, Dr. Jaffe and Dr. Clark—two highly credentialed, knowledgeable, and experienced experts in the field of clinical laboratory standards, procedures, and practices—opine that DDI's acceptance and reporting on provoked urine samples is not "fraud," "shady," a "trick," or "scam". (LR ¶ 66) In so concluding, these experts rely on their experience, training, and knowledge of clinical laboratory standards, procedures, and practice, including the facts that: (1) other clinical laboratories accept and report results for provoked urine samples (LR ¶ 67), (2) DDI's acceptance and

reporting is consistent with "applicable accrediting and licensing rules and regulations," as reflected by DDI's numerous federal and state certifications (*Id.*) and (3) CLIA specifically addressed and repeatedly rejected Defendant Barrett's "constant complaints" about DDI's acceptance and reporting on provoked urine samples after numerous "on-site inspections" (*Id.*) Moreover, these experts agree that, pursuant to commonly accepted industry practice, DDI is entitled to rely on the ordering physician's knowledge in ordering a provoked urine sample and then properly understanding and communicating DDI's reported results to her or his patient. (LR ¶ 68)

DDI's experts' testimony—explaining the propriety of DDI's clinical laboratory practices and therefore establishing the falsity of the Barrett Defendants' published statements—is undisputed. The Barrett Defendants disclosed no expert to rebut DDI's proffered expert testimony. Indeed, the Barrett Defendants possessed DDI's three liability expert disclosures well in advance of disclosing their own, yet only disclosed one "liability" expert, Dr. Ruha, an expert in snake and spider venom poisoning. (LR ¶ 51) And, as Dr. Ruha concedes, she is not an expert in clinical laboratory practices, standards, or reports. Specifically, in her deposition, Dr. Ruha conceded she is ***not "an expert*** in the field of regulations that would be ***applicable to clinical laboratories***.... [she] is ***not an expert in clinical lab report forms... I have no expertise about labs.***" (LR ¶ 52) (emphasis added) Accordingly, DDI's unrebutted expert testimony relating to the propriety of DDI's clinical laboratory practices further establishes the falsity of the Defendant Barrett's five published statements that DDI's provoked urine testing and reporting is a "fraud," "trick," or "scam" performed by a "shady lab."

Any reliance by the Barrett Defendants on Dr. Ruha's proffered opinions ***relating to clinical laboratory matters to attempt to rebut DDI's experts*** should be rejected for two reasons. First, Dr. Ruha's opinions relating to matters of clinical laboratory standards, practices,

and reporting are barred under *Daubert* and FRE 702 as "unqualified" and "unreliable." (*See* DDI's *Daubert* Motion) DDI incorporates its *Daubert* motion and arguments herein by reference thereto, rather than repeating them. For this reason alone, the Barrett Defendants may not properly rebut DDI's experts' testimony with Dr. Ruha's unqualified and unreliable opinions relating to matters of clinical laboratory standards and practice.

Second, even if this Court were to accept Dr. Ruha's clinical laboratory opinions as properly qualified and reliable (they are not), Dr. Ruha's opinions still do not genuinely rebut DDI's expert testimony that DDI properly accepts and reports on provoked urine specimens. Fairly summarized, Dr. Ruha's clinical laboratory opinion is that DDI's test report for provoked urine specimens ***may be potentially confusing to some (but not all)*** individuals because she has experience through her career with "dozens" of individuals who were confused by the DDI's format and reported findings. (LR ¶ 57-58)

Even if accepted as qualified and reliable, Dr. Ruha's aforementioned opinion hardly undermines DDI's experts' testimony that DDI properly accepts and reports on provoked urine samples. Dr. Ruha admits her opinion is based solely on her anecdotal and limited interaction with a "small fraction of the population" tested, compared to the tens of thousands of provoked urine specimens tested by DDI ***each year***. (LR ¶ 70) The fact that less than .1 percent of those tested might be confused by DDI's report format hardly establishes the truth of the Barrett Defendants' statements that DDI's reporting is a "fraud," "trick," or "scam." Indeed, Dr. Ruha concedes that ***only some*** (***not all***) ***individuals*** would potentially misunderstand DDI's test results report. (LR ¶ 71) (DDI's test result report for provoked urine sample "[c]ould be misleading to some but not to others," is only "potentially misleading," and is ***not*** misleading to her because she understands its disclaimer). Based on the foregoing, Dr. Ruha's clinical laboratory opinion about the potentially confusing nature of DDI's test report for provoked urine samples (even if accepted by the Court as

qualified and reliable, which it is not), does nothing to genuinely rebut DDI's expert opinions that DDI's test results report is consistent with industry standards and practices and therefore is not a "fraud," "trick," "scam," "shady." It cannot be overstated that the words "fraud" and "scam" or like words appear *nowhere* in Dr. Ruha's opinions.

Finally, a fourth basis also exists which establishes the falsity of the Barrett Defendants' statements: the Barrett Defendants' five libelous statements are based on a fundamentally erroneous understanding of clinical laboratory requirements. The factually false premise of the Barrett Defendants' libelous claims of "fraud," "scam," and "trick" is that ***DDI wrongly*** includes in its test results report for a provoked urine sample the reference ranges applicable to unprovoked urine. (LR ¶ 73) (Defendant Barrett complaining to CLIA about the "***fraud*** involved in the way [Doctor's Data's provoked urine] tests are reported" because DDI is "***using a false reference range to interpret their reports***?"); (LR ¶ 35) (Barrett Article, "*How the 'Urine Toxic Metals' Test Is Used to Defraud Patients*", p.1) (stating that DDI's test results report for a provoked urine sample is "used to defraud patients" and is a "scam" because DDI's "report classifies the man's lead and mercury levels as 'elevated' because they are twice as high as the upper limit of their 'reference ranges'," which is "misleading" because the "reference range is based on non-provoked tests")

Indeed, Defendant Barrett actually testified that if DDI were to remove the unprovoked urine reference ranges from its results report applicable to provoked urine, he would have ***no criticism*** of DDI. Specifically, when asked whether he would have any criticism of DDI if it omitted any reference range information on its test results report for unprovoked urine, Defendant Barrett testified, "I don't think I'd have an issue with Doctor's Data, I'd have an issue with the doctor who does the test." (LR ¶ 74)

However, this underlying premise—on which the Barrett Defendants rest their libelous claims of "fraud," "trick," and "scam" against DDI—is a factual impossibility and illegality, thereby

also demonstrating the falsity of their libelous statements. Indeed, apparently ignored by the Barrett Defendants and unknown to Dr. Ruha, ***reference ranges are required on clinical laboratory reports as a matter of federal law*** (42 CFR 493.1291), and there is no scientifically established "reference range" for *provoked* urine. (LR ¶ 30) As a result, it is an acceptable, indeed mandated, industry practice to include the reference range applicable to unprovoked urine on any test results report for a provoked urine sample with accompanying qualifying language—in bold lettering—stating that the reference range is inapplicable if the test was of a provoked urine specimen. (LR ¶ 30-31) Indeed, both CLIA and DDI's clinical laboratory experts concur on this point. (LR ¶ 30-31; 36) In contrast, like Defendant Barrett, the Barrett Defendant's expert, Dr. Ruha, did not know this critical industry practice/requirement:

> Q. Are you aware of whether reference intervals are required to be reported on lab tests for non-provoked urine samples?
>
> A. I am not aware if they are required.
>
> Q. Okay. Same question for provoked urine testing. Are you aware one way or the other as to whether reference intervals are required as a matter of regulation or law to be included on a test report form for provoked urine samples?
>
> A. I am not aware if they are required.

(LR ¶ 77) Accordingly, because the Barrett Defendants' libelous statements against DDI rest on a fundamentally erroneous (indeed, impossible) premise that DDI ***wrongly*** includes reference ranges for unprovoked urine in its test results report for provoked urine samples, this too proves the falsity of their libelous claims that DDI's test results report for provoked urine testing is a "fraud," "trick," "scam," and "shady."

In sum, DDI has proven the absence of any genuine issue of material fact relating to the elements of libel *per se*. Consequently, summary judgment is proper on DDI's Count 5, as it relates to the five statements identified above.

B. Summary Judgment Is Proper As To The Barrett Defendants' Affirmative Defenses.

DDI also is entitled to summary judgment on the Barrett Defendants' two affirmative defenses, statute of limitations and laches. (Crt. Docket #225) The Barrett Defendants have no viable statute of limitations defense. The statute of limitations for libel is 1 year.[4] DDI filed this lawsuit on June 18, 2010. (Crt. Docket #1) The Barrett Defendants made all of the foregoing libel *per se* statements either within a year of DDI's filing or *after* DDI's filing. In particular, the Barrett Defendants' libelous Statements 1-3 above were published in the Barrett Defendants' article, *"How the 'Urine Toxic Metals Test' is Used to Defraud Patients."* (LR ¶ 14-16; 78) Although this article was originally published in February 2009, the Barrett Defendants updated and republished it in March 2010 (just months before DDI's filing), with each of the foregoing three libelous statements. (LR ¶ 78); *Wathan v. Equitable Life Assurance Soc.*, 636 F. Supp. 1530, 1533 (C.D. Il. 1986) (republishing libelous article with "subsequent distribution [of the article] gives rise to a new cause of action"). Similarly, the Barrett Defendants' other libelous statements were published in March 2010 (Statement 4) and July 2009 (Statement 5). (LR ¶ 79) The same is true for all of the allegedly libelous statements alleged in DDI's complaint. (LR ¶ 80) Accordingly, the Barrett Defendants' have no viable statute of limitations defense and summary judgment is proper as to this frivolous claim.

Summary judgment also is proper as to the Barrett Defendants' asserted affirmative defense of laches. A party seeking to employ the doctrine of laches as an affirmative defense has the burden of proving: (1) the plaintiff "negligently failed to assert an enforceable right within a reasonable period of time," and (2) the defendants were "prejudiced by the delay in

[4] Defendants cite Section 13-201 of the Illinois Code of Civil Procedure. [#225, p. 41] However, pursuant to the ruling of this court on 12/2/2011, Defendants may avail themselves only of defenses under North Carolina law. [#85] *Supra*, 3. However, the SOL happens to be 1 year in North Carolina. N.C. Gen. Stat. § 1-54(3).

bringing the action." *Sunbelt Rentals v. Head & Engquist Equipment, Inc.*, 174 N.C.App. 49, 63, 620 S.E.2d 222, 232 (2005).

Applying the foregoing standard, the Barrett Defendants cannot satisfy their burden of proving laches. DDI's filing within the applicable 1-year statute of limitations is generally considered *per se* reasonable. *Irby v. Freeze*, 206 N.C. App. 503, 511, 696 S.E.2d 889, 892 (2010) (acknowledging that as a general rule, courts "measure laches by the pertinent statute of limitations wherever the latter is applicable to the situation and not to regard the delay of the actor to assert the right within that period effective as estoppel, unless upon special intervening facts demanding that exceptional relief"). Moreover, the Barrett Defendants can cite to no "special intervening facts" demanding any "exceptional relief," which typically requires a showing of prejudice by the delay in bringing the action. *Id.* Here, there is neither delay nor prejudice, particularly considering the Barrett Defendants have not altered their behavior: The same actionable Internet and web-site publications are still found in the same places. Indeed, the Barrett Defendants have affirmatively republished (or cited anew in different publications) their libelous statements since DDI's filing. (LR ¶ 78-80) Accordingly, this Court also should grant summary judgment against the Barrett Defendants' likewise frivolous assertion of laches as an affirmative defense.

V. CONCLUSION

For all the foregoing reasons, Plaintiff Doctor's Data, Inc. respectfully requests that this Court enter summary judgment against the Barrett Defendants on its Count 5 (Libel *Per Se*) and the Barrett Defendants' affirmative defenses of statute of limitations and laches.

Respectfully submitted,

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