

ORIGINAL

IN THE SUPREME COURT OF OHIO

MARY McGOWAN, M.D.,

: Case No. 2015-1756

Appellant,

:

vs.

On Appeal from the Hamilton
County Court of Appeals, First
Appellate District

MEDPACE, INC.

:

Appellee.

:

MERIT BRIEF OF APPELLEE MEDPACE, INC.

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I. INTRODUCTION

The Merit Brief of Appellant Mary McGowan (“McGowan”) is useful for only one reason. It illustrates, yet again, McGowan’s unwillingness even to admit, much less take any personal responsibility for, the succession of colossal blunders that she made while employed at Medpace, Inc. (“Medpace”) and that ultimately caused her own professional demise. In particular, she still refuses to acknowledge that she improperly, and mistakenly, accused Dr. Evan Stein (“Stein”) of insurance fraud and other illegal conduct. She still refuses to acknowledge that her accusations pertained solely to Stein’s conduct of his private medical practice, and not to Medpace’s entirely separate clinical research business. She still will not admit that Medpace terminated her employment, not because she voiced concerns about Stein’s private medical practice, but because of her gross and repeated insubordination. She still refuses to acknowledge that Medpace afforded her several opportunities to correct her self-destructive behavior, all of which she deliberately ignored. She ignores the fact that a jury in the United States District Court unanimously found her guilty of slandering Stein by making in public the very same false accusations she claims now protect her. In short, McGowan continues to portray herself as a victim of retaliation when, in fact, she lost her job at Medpace solely because of her own poor judgment and disastrous choices.

Medpace recognizes this appeal does not depend on the resolution of disputed facts. It revolves instead around McGowan’s mistaken contention the First Appellate District’s decision is contrary to this Court’s ruling in *Greeley v. Miami Valley Maintenance Contrs., Inc.*, 49 Ohio St.3d 228, 551 N.E.2d 981 (1990). Nonetheless, it is critical to highlight McGowan’s profoundly misleading, and at times demonstrably false, portrayal of the facts, particularly in light of her attempt to persuade this Court to approve a vast expansion of the limited exceptions to Ohio’s long-standing employment at-will doctrine.

II. STATEMENT OF FACTS

A. Medpace's Business

Medpace is a global clinical research organization, headquartered in Cincinnati, which is engaged by pharmaceutical companies to conduct studies of medications and medical devices in human test subjects. (Tr. 800:4-801:6). Because of the highly regulated nature of its business, Medpace is required to, and does, scrupulously comply with an extensive array of complex rules and regulations. (Tr. 855:5-9; 860:1-861:5). Medpace's clients, and government watchdogs such as the United States Food and Drug Administration, routinely audit Medpace to certify its adherence to requirements for everything from patient charts to informed consent documentation to compliance with clinical trial protocols. (Tr. 860:1-24). Medpace also has in place strict policies that require its employees to report immediately any events or circumstances which might run afoul of Medpace's compliance obligations (Tr. 861: 15- 865:18).

Medpace's Clinical Pharmacology Unit (the "CPU") performs Phase I clinical trials, which are studies of drugs being tested, for the first time, on humans (Tr. 802:10-23; 804:15-806:3). Medpace also monitors investigative studies at sites throughout the country, which focus on late-stage clinical trials of drugs on humans afflicted with the condition the drugs are designed to treat. Finally, Medpace operates the Metabolic and Atherosclerosis Research Center ("MARC"), which is located in the same building as the CPU and which conducts Phase II-IV clinical trials specifically for lipid, or cholesterol disorders. In 2011 MARC had only five employees and just one principal investigator ("PI") – Stein, who pharmaceutical companies hired to supervise drug studies. (Tr. 817:2-18). Stein operated MARC, and served as its Director, primarily for the benefit of his private practice patients; that is, so he could enroll certain at-risk

patients in clinical trials that might improve their condition. (Tr. 811:14-25).¹ In fact, all the individuals who participated in MARC studies were Stein's own private practice patients. (Tr. 813:17-22).

B. Stein's Private Practice

Stein also maintained his own private practice under the name "Cholesterol Treatment Center" ("CTC"), through which he treated his own patients with cholesterol disorders. (Tr. 485:11-15; 813:6-16; 867:17-19). Although located on the Medpace campus, CTC was an entirely separate organization owned by Stein. *Id.* At trial McGowan conceded that CTC had no affiliation with Medpace. (Tr. 305:9-19). In her brief, McGowan now entirely glosses over those important distinctions in her effort to hold Medpace vicariously responsible for the manner in which Stein operated CTC.

C. Medpace's Search for an Executive Director

Before Medpace hired McGowan, the Director of the CPU and the Director of MARC were separate positions. (Tr. 814:6-815:9). In the spring of 2011, Medpace decided to search for someone who could serve as the Executive Director of both the CPU and of the much smaller MARC (also referred to collectively as the Medpace I-IV Clinics) (Tr. 815:10-816:13). Stein hoped this same individual would eventually also take over his private practice at CTC, and his responsibilities as a PI at MARC, so he could retire. (Tr. 806:4-14; 810:9-17; 813:6-16; 823:23-824:2). Stein had become acquainted with McGowan over the years through medical

¹ McGowan insisted both before and at trial that Stein's referral of private patients to MARC violated the federal anti-kickback law and the Physician Self-Referral (Stark) Law. (Tr. 392:7-15). McGowan eventually admitted – though only after she publicly had accused Stein of violating federal law – that she had been mistaken and that her accusations were entirely unjustified. *Id.* There also was never any connection between Stein and Medpace regarding those unfounded charges.

conferences, and in connection with Medpace's and his own search, he contacted McGowan to see if she knew of any suitable candidates. When she expressed an interest in the position herself, Stein forwarded her name to Dr. August Troendle ("Troendle"), the CEO of Medpace and the person to whom McGowan would directly report if hired (Tr. 821:14-822:11; Tr. 831:21-832:5; Ex. 4). Troendle subsequently interviewed McGowan and Medpace ultimately decided to hire her as the Executive Director of both the CPU and MARC. (Tr. 830:9-11).²

D. McGowan's Accusations Regarding Stein

In addition to assuming responsibility for the CPU and MARC, McGowan agreed, as Stein had hoped, to take over Stein's separate, private practice at CTC. (Tr. 842:24-843:5). In the course of that transition, McGowan learned of certain aspects of Stein's private practice at CTC about which she disagreed: (1) his method of writing prescriptions; and (2) the manner in which he maintained patient charts. (Tr. 337:19-338:6).³

² Medpace is compelled to note that in her brief McGowan touts herself as "one of the most highly-regarded experts in the treatment of cholesterol disorders in the country." (McGowan Merit Brief, p. 2). However, the record contains no such testimony or other evidence. Rather, the transcript references McGowan cites in support of her pronouncement provide only an explanation of Phase I, II and III clinical trials, the logistics surrounding her family's possible move to Cincinnati, and a citation without discussion, to Stein's letter to his patients about McGowan joining his practice. (Tr. 293:7-302:6) (cited by McGowan). This disturbing mischaracterization of the record – which occurs throughout her brief – is symptomatic of McGowan's self-serving and often fictional characterization of the events surrounding her rise and fall at Medpace.

³ McGowan claims in her brief that she first learned of Stein's prescription writing practices because she was "repeatedly asked by patients and CTC/MARC staff to refill prescriptions which Stein had originally written. . . ." (McGowan Merit Brief, p. 3, citing Tr. 334:3-345:1). There is no support whatsoever in the record for that statement. (Tr. 334:3-345:1). The only reference to refilling prescriptions in the testimony cited by McGowan is that as prescriptions needed renewal she would review the patient's chart and "sometimes it would say: Cut the pill in half." (Tr. 334: 18- 335:13). Moreover, McGowan admitted at trial that no one **ever** asked her to write a prescription for what she believed to be an incorrect amount (Tr. 458: 16-23). McGowan also conceded that as soon as she assumed responsibility for CTC she was free to write prescriptions in any manner she chose (Tr. 458: 24-459: 2). She even could have shut down CTC if she had wanted. (Tr. 970:9-971:1).

1. Stein's Prescription Practices

McGowan testified at trial she had concerns for “patient safety” with regard to Stein’s prescription writing practices for his private practice patients and, in particular, his practice of directing some patients to split pills. (Tr. 339:8-340:5; 477:18-22). The uncontroverted evidence at trial, however, demonstrated that “pill-splitting” is a practice commonly utilized by physicians, and is endorsed – and in some cases even encouraged – by insurance companies as a legitimate means of providing cost savings for patients. *Id.*; Tr. 481-492; 860:19-861:5; 866:18-867:16; Tr. 483: 14-22; Medpace Ex. 190; Tr. 605:17-608:5. Despite her professed concerns for “patient safety,” McGowan did not identify in her Complaint, in any of her motions or other filings, or at trial, any specific statute, rule, regulation, protocol or practice that justified those concerns.

McGowan testified at trial that, in her opinion, “pill-splitting” also defrauds insurance companies in violation of R.C. 2913.47. (Tr. 468:5-470:6). That statute, however, governs the submission of claims to insurance companies. R.C. 2913.47(B)(1). It has no any application to Medpace, which never submitted any insurance claims on behalf of Stein or any of his private practice patients. (Tr. 813:12-16). Indeed, McGowan conceded that her concerns had nothing whatsoever to do with Medpace, but instead centered on Stein’s **personal** prescription writing practices in connection with Stein’s **private practice** at CTC. (Tr. 603:2-11; 457:16-23)⁴.

2. Stein's Charting Practices

Whenever one of Stein’s patients enrolled in a MARC study, his office combined the private practice treatment chart and the MARC study chart for that patient. *Id.* McGowan

⁴ McGowan also testified at trial that she independently had “researched” R.C. Chapter 3901 and concluded Medpace had violated that statute. (Tr. 469:22-470:6). However, she never demonstrated that statute, which regulates acts within the private insurance industry, has any application to Medpace. She now has entirely abandoned that argument on this appeal.

claimed this administrative practice violated The Health Insurance Portability and Accountability Act of 1996 (HIPAA). (Tr. 341:4-16; Tr. 343:5-21). The uncontroverted evidence at trial disproved her accusations.⁵ Dessy Dimova (“Dimova”), a study coordinator at MARC, testified at trial that combining the patient charts is critical because when a pharmaceutical company evaluates the safety and efficacy of a new drug in a study subject, “we need to have access to all the information . . . [T]here are many inclusion/exclusion criterias, which can exclude the patient if we don’t have certain information.” (Tr. 1197). Further, McGowan admitted at trial that Medpace’s Director of Quality Assurance specifically informed her that all of Stein’s patients who had enrolled in MARC studies had signed consent forms expressly authorizing the combination of their charts. (Tr. 494:4-498:25; Medpace Ex. 122).

E. McGowan’s Disregard of Medpace Reporting Protocols

When McGowan decided to voice her concerns about Stein’s private practice, she made two enormous mistakes. First, she ignored the fact that Medpace had nothing whatsoever to do with Stein’s private practice.⁶ Second, even if McGowan believed she had an obligation to report her concerns to Medpace rather than simply change Stein’s old practices, she did not follow Medpace’s established policies for reporting compliance concerns. Medpace must track any potential compliance deficiencies and, therefore, the company requires **all** employees to report their concerns immediately and directly to the company’s compliance officer or to its Director of Human Resources. (Tr. 1089:15-21; Medpace Ex. 10). As McGowan acknowledged at trial, Medpace’s compliance policies expressly: (1) require employees to report any concerns

⁵ Stein’s subsequent successful prosecution of a defamation case against McGowan further illustrates the spurious nature of her claims. *See infra* at pp. 13-14.

⁶ To this day McGowan never has fully explained why she did not address her concerns with Stein, other than to say she did not want to “embarrass” him. (Tr. 466:6-12). Evidently her professed sensitivities in that regard did not extend to repeatedly accusing him, in public, of fraud.

of fraud or misconduct, or risk termination for failing to report; and (2) direct employees not to disclose any uninvestigated suspicions to the staff. (Tr. 505:15-506:10). McGowan inexplicably refused, repeatedly, to follow these company compliance policies, despite being a member of Medpace's senior management team. (Tr. 458:6-22; 918:16-25).

1. July 22, 2011 Medpace Staff Meeting

Purposely ignoring Medpace's compliance policies, McGowan took it upon herself at a July 22, 2011 Medpace staff meeting with low level employees to accuse Stein of insurance "fraud." (Tr. 467:18-468:4).⁷ Shocked by McGowan's sensational accusations, MARC Study Coordinator Dimova spoke up in the meeting and indicated that, in her opinion, McGowan should not air her allegations with Medpace staff members because her concerns related to Stein's private practice, and not to MARC or Medpace:

She asked me if I feel fine, because I had kind of a surprised look on my face. I said I feel fine, but it's not our place to be in the room. I mentioned that Dr. Stein should be the one who should know about those concerns. She should discuss them with him, not us.

(Tr. 1180:17-24). Lindy Bussell ("Bussell"), another Medpace employee, provided similar testimony: "And then she spoke about Dr. Stein's charting and said that he had had some unethical, illegal and fraudulent activities in his charting. And with that, I didn't personally want to be involved in that because that didn't have anything to do with me." (Tr. 1251:1-6). Some of

⁷ In yet another example of McGowan's mischaracterization of the record, she claims in her brief that she called the meeting "to explain that she had been repeatedly asked to sign unlawful/unsafe prescriptions." (McGowan Merit Brief, p. 4, citing Tr. 334:3-345:14). The cited pages of the transcript do not contain any such testimony. And there is no evidence anywhere else in the record that anyone ever tried to persuade McGowan to write prescriptions in any certain way. McGowan's actual testimony is that the purpose of the staff meeting was to "let people know, really in no uncertain terms that things had to change, that we had to change the way we wrote prescriptions. We had to change the way we handled the charts." (Tr. 343:5-12). Rather than simply instruct the staff on how she intended to write prescriptions and manage charts – which she had every right to do – McGowan instead took the entirely needless, and reckless, step of accusing Stein of insurance fraud. (Tr. 467:18-468:4).

the staff members at the meeting found McGowan to be purposely threatening and intimidating. (Tr. 1190:1-2;1263:1-13).

Certain Medpace employees who attended the July 22 staff meeting alerted then in-house counsel, Kay Nolen (“Nolen”), about the accusations McGowan had made. Nolen, in turn, promptly reported them to Troendle. (Tr. 1192:3-16; 971:4-22; 851:8-19 & Ex. 107). In response, Troendle instructed Nolen to meet with the staff members and also to schedule a meeting with McGowan. (Tr. 852:8- 853:17 & Ex. 107).⁸ Troendle also asked Nolen to investigate the substance of McGowan’s allegations. (Tr. 852:13-17).

When Stein learned, second hand, that McGowan had accused him of fraud in front of Medpace staff members, he understandably decided he no longer wanted to transition to McGowan either his duties as a PI at MARC or his private practice at CTC. (Tr. 897:25-898:7). Consequently, Stein immediately resumed seeing his private patients at CTC and resumed his PI responsibility for the studies at MARC, which had all come directly to him as the investigator. *Id.* Contrary to McGowan’s conspiracy theories and insinuations, Stein did not, and could not, undermine McGowan’s position as the Executive Director of the CPU and of MARC since he had no authority to interfere with her employment by Medpace. (Tr. 898:15-899:7).

2. July 27, 2011 Medpace Management Meeting

On July 27, 2011 McGowan met with Troendle, Nolen, and Tiffany Khodadad (“Khodadad”), Medpace’s Director of Human Resources. At the meeting, McGowan reiterated

⁸ Again, McGowan misstates the record in her brief. She now disingenuously suggests that on July 26 she asked to meet with Medpace’s senior management: “Consistent with” Medpace’s “directives for reporting suspected violations,” she “sent an email asking for an immediate meeting to address Stein’s unlawful prescription practices and his retaliation.” (McGowan Merit Brief, p. 5, citing Tr. 349:5-350:11). In fact, Medpace already had called the meeting to address McGowan’s accusations and behavior four days earlier.

her concerns about Stein's pill-splitting and his combination of patient treatment and study charts (Tr. 1081:23-1082:4); Tr. 985:4-11).⁹ In so doing, McGowan utterly ignored the fact that all of Stein's patients had signed consent forms authorizing the combination of their charts.¹⁰

Troendle agreed with McGowan about the critical need for Medpace personnel to comply with all applicable legal and regulatory requirements. (Tr. 855:3-17). In fact, Troendle emphasized that McGowan had an affirmative obligation to inform him of any perceived problems in that regard. (Tr. 854:22-855:2). Troendle did not agree, however, with McGowan's unilateral decision to make unproven accusations in the presence low-level Medpace staff members (Tr. 858:2-5). He explained his concerns to her as follows:

. . . I told her I was happy and glad she brought this to our attention, that we would fully investigate it. I didn't want – you know, we're a highly regulated industry. We have audits all of the time of our unit. We don't want the auditors to come in and find practices that are inappropriate. We wanted to take action and clean up anything that was done, to rectify it, and to take whatever action with Evan was necessary. But the first thing is to find out what the facts are, find out the legal issues are and define what was going on.

(Tr. 855:5-17).

* * * * *

⁹ McGowan's brief suggests, for the first time in this case, that she also complained during the July 27 meeting about the "exposure" of patient charts (McGowan Merit Brief, p. 7). In fact, her testimony pertains only to her observations that patient charts had been placed outside of patient treatment rooms in preparation for the physician's visit with the patient. *Id.* There is no evidence in the record that McGowan raised these concerns either at the July 27 meeting, or in any other meeting with Medpace management.

¹⁰ The citation in McGowan's brief which supposedly supports her concern (McGowan Merit Brief, p. 4, citing Tr. 497:2-499:3), in fact, directly refutes it. The e-mail message from Medpace's Quality Assurance Director, referenced above, explicitly informs McGowan that the combination of patient charts is permissible with signed patient consent forms. It also tells her that if she chose to maintain separate files – which she had the right to do – the FDA still would require cross-access, "or we could be cited with refusal to grant access." (Tr. 497:10-25; Medpace Ex. 122). He told her that "most sites keep the types of details below you mentioned in one file. Per GCP, we have to have permanent review of all medical records . . ." (Tr. 498: 9-15 & Medpace Ex. 122).

And I told her, tell the staff to prescribe – you’re going to prescribe differently. The staff had nothing to do with prescriptions anyway, but tell them anything you feel uncomfortable about, you shouldn’t be following some prior practice of someone else. Do it your own way, but just don’t talk to staff and accuse other colleagues of improper activity until it’s investigated and adjudicated.

(Tr. 857:15-19).

Khodadad testified at trial that she shared Troendle’s concerns, and that while McGowan had the right to express her opinions at an appropriate time and place, she had no right to accuse Stein of fraud and other illegal conduct in a Medpace staff meeting. (Tr. 1092:1-9). Khodadad also testified that McGowan did not appear at all receptive to Troendle’s instructions; rather, she was “argumentative” and did not seem to understand Troendle objected to her approach with the staff. (Tr. 1092:9-17).

Despite the highly inappropriate forum and manner in which McGowan had raised her concerns, and his own private skepticism,¹¹ Troendle did not dismiss those concerns: “I certainly wanted it investigated and looked at by someone who knew the details of the law.” (Tr. 868:7-10). To that end, Troendle told McGowan she should feel free to pursue her complaints through proper channels. (Tr. 855:856:1; 859:1-9). Troendle also explained that he instructed Nolen to investigate any legal compliance issues. (Tr. 852:15-20; 868:17-22; 869:5-12). McGowan admitted that Nolen, in turn, suggested to McGowan that she contact the Ohio State Board of Pharmacy to discuss her concerns.¹² (Tr. 361:4-21). Troendle reminded McGowan that, as the new Executive Director of the Medpace I-IV Clinics, she had the authority to set its policies and

¹¹ Troendle’s own health insurance company had encouraged him to split his cholesterol medication (Tr. 866:18-867:3) and none of the audits described above had ever identified any problems with the manner in which patient charts were maintained. (Tr. 860:25-861: 10; Tr. 1198:18-1199:9).

¹² At trial McGowan offered uncorroborated hearsay testimony to the effect that, at some point before the initial July 22 meeting, she had contacted a health care attorney to confirm her concerns about Stein. McGowan did not, however, call that attorney as a witness at trial or present any other evidence to establish that the conversation ever took place.

practices including with respect to prescription writing, patient charts and the acceptance of patient referrals (which McGowan, in fact, subsequently did). (Tr. 857:20-858:5). Troendle also told McGowan that, although he could not force Stein to restore her as PI on Stein's own MARC studies, she would be the designated PI on any future studies that she recruited to MARC.

Despite these reassurances by Troendle, during the July 27 meeting McGowan continued to complain about Stein's decision to resume treating his private practice patients – even though Troendle had no ability whatsoever to dictate to Stein how he should manage his private practice. As Troendle testified: “I didn't think it was appropriate for me to get involved in what patients, what doctor they should see.” (Tr. 891:3-8).

Nonetheless, Troendle empathized with McGowan, and told her he realized Stein at times could be “tough” and “demanding.” (Tr. 907:20-24). He suggested to McGowan that if she still wanted to take over Stein's private practice, as she and Stein originally had planned, she should apologize to Stein – not for questioning his practices, but for her indiscriminate outbursts:

Q. And did you mean that she should apologize for having concerns or raising the concerns?

A. Of course not, no . . . Again, all I told her was that I was very glad she brought up these concerns. We would look into them. It was very important that we address them appropriately for the appropriate channels. What she should be apologizing for is going to the staff and bad-mouthing him in front of the staff without having examined or appropriately investigated the situation.

(Tr. 895:6-896:12).

Troendle also told McGowan that he wanted her to focus on the much larger and more important business of the CPU. (Tr. 911:18-912:3). Indeed, the uncontroverted evidence at trial is that Troendle told McGowan she could, if she so desired, shut down both CTC right away and MARC once Stein's current studies had ended. (Tr. 825:17-25). Shortly after the July 27 meeting Troendle and McGowan also discussed her desire to hire several new Medpace employees for

the CPU, including an additional nurse coordinator. (Tr. 912:4-16). Troendle agreed and indicated they should talk about McGowan's request to hire a third new employee when she returned from vacation on August 15 *Id.* & Ex. 142. Most importantly, even after all her inappropriate conduct, McGowan's salary, benefits, job title, and assigned duties and responsibilities did not change in any respect. (Tr. 910:3-7).

F. McGowan Accuses Troendle of Lying

Despite his directives, Troendle received reports that McGowan continued to speak to Medpace staff members about Stein's supposed fraud. (Tr. 918:2-15). One Medpace employee who reported to McGowan testified that she made other inappropriate comments, such as calling Stein a "64 year old" "cowboy from South Africa" who needed to "move on and retire." (Tr. 1261:12-1262:8). Consequently, Troendle again asked to speak with McGowan after an August 17, 2011 staff meeting.¹³

At their meeting Troendle again admonished McGowan that she should raise any concerns about Stein through appropriate channels, and that she should not discuss her concerns with Medpace staff members. (Tr. 918:16-20). McGowan again refused to heed Troendle's instructions. (Tr. 918:21-25). Furthermore, this time McGowan also accused Troendle of trying to intimidate her, and accused him of being a "liar," contending that Troendle had called Stein an "asshole" in their prior meeting and then lied about it in a subsequent email. (*Id.*; Tr. 917). McGowan admitted that Troendle finally became angry when she accused him of lying

¹³ McGowan represents in her brief that Troendle asked her to stay "to tell her that she needed to apologize to Stein. . . ." (McGowan Merit Brief, p. 7, citing Tr. 474:16-475:1). In fact, McGowan did not testify about the details of her August 17, 2011 meeting with Troendle at any time during her direct examination, and she made no mention of this alleged request that she apologize during any of her discussion of that meeting on cross examination. (Tr. 533:6-542:10).

(Tr. 540:1-6) and her own notes from the meeting indicate Troendle was “clearly furious.” (Tr. 536:7-20 & Medpace Ex. 152). McGowan conceded at trial that she “snapped” and that her behavior toward Troendle could be legitimately characterized as “confrontational.” (Tr. 534:2-535:8; Tr. 534: 10).

McGowan’s unyielding defiance, and unprovoked attack on Troendle’s integrity, proved to be the final straws. After their August 17 meeting, an exasperated Troendle reluctantly concluded McGowan could no longer serve as an executive with the company:

I’d hired Dr. McGowan to be a key member of our leadership team to head an important business unit and help grow it with my support, and she was unwilling or unable to deal with issues that came up in a professional manner. She refused to take my proper direction in not talking to staff about issues like this. We should have an investigation and evaluation and we can’t indict them, try them, and then punish them just because, you know, she feels one way. That, you know, she was being insubordinate. She wouldn’t listen to me. She didn’t care. She didn’t think I had any authority to tell her what to do and thought that she was free to act as she wanted to. And, also, she was extremely confrontational. You know, she was calling me a liar. She’s threatening staff. She’s refusing to listen to my concerns about anything. She was – I left feeling – this is someone I can’t trust, I can’t work with, I can’t mentor, which is a critical part of her job trying to take over this business. She doesn’t have familiarity with it; that there’s no way I can make it work.

(Tr. 923:11-924:11). The next day Medpace terminated McGowan for her insubordinate and confrontational behavior. (Tr. 924:12-15).

G. Stein’s Defamation Case

After McGowan’s departure from Medpace, Stein filed suit in federal court for defamation based on her accusations, in the presence of Medpace staff members, that he had engaged in fraudulent conduct. *Stein v. McGowan*, Civil Action No. 1:12cv605 (S.D. Ohio). The case proceeded to trial and on February 25, 2015 the jury returned its unanimous verdict in favor of Stein and awarded him \$40,000 in compensatory damages. *Id.* at Doc. #77. The jury also found “by clear and convincing evidence that McGowan’s defamatory statement(s) were made

with ill will, anger, hatred, [and] reckless disregard of the consequences or with intent to injure Stein or to harm his reputation” and awarded him an additional \$80,000 in punitive damages plus his attorneys’ fees. *Id.*

III. ARGUMENT IN RESPONSE TO PROPOSITIONS OF LAW

Appellant’s Proposition of Law I: Under this Court’s Jurisprudence, a Greeley Claim Does Not Derive Solely from Statutes or Other Sources That Impose an Affirmative Duty on an Employee to Report a Violation, Prohibit an Employer from Retaliating Against an Employee Who Reports a Violation, or Protect Public Health and Safety.

A. **The First District Decision Serves Existing Public Policy and Is Consistent With Greeley**

The employment-at-will doctrine long has been, and remains, an important pillar of public policy in the State of Ohio. *Mers v. Dispatch Printing Co.*, 19 Ohio St.3d 100, 483 N.E.2d 150 (1985). Twenty-five years ago, this Court crafted a limited **exception** to the employment-at-will doctrine and ruled that an at-will employee may maintain a cause of action for wrongful discharge if the employee is discharged or disciplined in violation of a statute or a clearly articulated public policy. *Greeley v. Miami Valley Maintenance Contrs., Inc.*, 49 Ohio St.3d 228, 551 N.E.2d 981 (1990). Since then, a relentless succession of plaintiffs have urged Ohio courts, including this Court, to expand that limited exception, in some cases to the point where, as a practical matter, the employment-at-will doctrine would cease to exist. McGowan joins that long list of former employees and asks this Court to approve what the First District Court of Appeals in its Opinion refused to sanction – a “destruction” of one of Ohio’s “most important public polic[ies].”¹⁴ *McGowan vs. Medpace*, 1st Dist. Hamilton Nos. C-140634 and C-140652, 2015-Ohio-3743, 42 N.E.3d 256. As the First District wisely recognized:

¹⁴ The Ohio Employment Lawyers Association (“OELA”) has filed in support of McGowan a nearly identical *amicus* brief, the import of which should be entirely discounted inasmuch as McGowan’s counsel is the chair of OELA’s Cincinnati branch.

With the continued and ongoing explosion in statutes, governmental regulations, and policies found under the Ohio Revised Code and the Ohio Administrative Code, as well as federal laws and regulations, if exceptions to the at-will-employment doctrine are not narrowly construed, the so-called “exceptions” will speedily and overwhelmingly undermine and eliminate the concept of at-will employment in this state.

Id. at ¶ 22.

Since its decision in *Greeley*, this Court has provided additional guidance concerning when and how the limited exception to Ohio’s employment-at-will doctrine should be applied. In particular, it has held that to establish a claim for wrongful termination in violation of Ohio public policy, the employee must prove: (1) a clear public policy exists and is manifested in a state or federal constitution, statute, or administrative regulation, or in the common law (the clarity element); (2) the employee’s dismissal would jeopardize that public policy (jeopardy element); (3) the employee’s dismissal was motivated by conduct related to the public policy (the causation element); and (4) the employer lacked an overriding legitimate business justification for the dismissal (the overriding justification element). *See, e.g., Collins v. Rizkana*, 73 Ohio St.3d 65, 69-70, 652 N.E.2d 653 (1995). The jeopardy and clarity elements are questions of law and policy to be decided by the court. *Kulch v. Structural Fibers, Inc.*, 78 Ohio St.3d 134, 1997-Ohio-219, 677 N.E.2d 308 (1997).

To satisfy the clarity element, “a terminated employee must articulate a clear public policy by citation to specific provisions in the federal or state constitution, federal or state statutes, administrative rules and regulations, or common law.” *Dohme v. Eurand America, Inc.*, 130 Ohio St.3d 168, 2011-Ohio-4609, 956 N.E.2d 825, ¶¶ 18, 24. Courts must not search for sources of public policy that an employee did not identify, even if those sources may support the employee’s claim. *Id.* at ¶ 23. Rather, this Court has imposed a strict, substantive burden on a plaintiff who asserts a wrongful discharge claim based on a violation of public policy to identify

with specificity the law that reflects that policy. *Id.* at ¶¶ 19-24 (“[A] court may not presume to *sua sponte* identify the source of that policy. . . . An appellate court may not fill in the blanks on its own motion.”).

To satisfy the jeopardy element, a court also must inquire “into the existence of any alternative means of promoting the particular public policy to be vindicated by a common-law-wrongful-discharge claim.” *Wiles v. Medina Auto Parts*, 96 Ohio St.3d 240, 2002-Ohio-3994, 773 N.E.2d 526, ¶ 15. In other words, the courts will not provide a remedy for an alleged wrongful discharge in violation of public policy if there already exists a statutory remedy that adequately protects society’s interests by discouraging the wrongful conduct. *Id.* Therefore, to satisfy the jeopardy element, an employee must demonstrate that without a common law tort claim for wrongful discharge, the public policies advanced by the statute or policy at issue would be compromised. *Id.*

B. The Application of *Greeley* in the First District

In its application of *Greeley*, the First District has determined that where, as here, a wrongful discharge claim is not based on the Ohio whistleblower statute, the employee must identify not just any public policy, but a specific public policy that (1) places an affirmative duty on the employee, separate from the whistleblower statute, to report the violation; (2) specifically prohibits the employer from retaliation; or (3) protects the public’s health and safety. *Dean v. Consol. Equities Realty #3, L.L.C.*, 182 Ohio App.3d 725, 2009-Ohio-2480, 914 N.E.2d 1109, ¶ 11 (1st. Dist.). *Dean* is based on the First District’s prior ruling in *Hale v. Volunteers of America*, 158 Ohio App.3d 415, 2004-Ohio-4508, 816 N.E.2d 259 (1st Dist.), which the First District issued “[a]fter analyzing the Ohio Supreme Court’s discussion of public policy independent from the whistleblower statute, as well as the case law from our sister appellate districts” *Id.* at ¶ 44. The First District has stated that “[u]nderlying our decision in *Hale*

was the recognition that any exception to the at-will doctrine should be narrowly applied.” *Dean* at ¶ 12. The First District noted Ohio’s general policy against fraud, but found that the public policy underlying the consumer statute at issue “is not manifested clearly enough to warrant abrogating the at-will employment doctrine.” *Id.*

Contrary to McGowan’s contention, the *Hale* and *Dean* cases do not create “new criteria” for the clarity element under *Greeley* claim. Rather, they apply the *Greeley* criteria in a manner that is consistent with the prior guidance of this Court and with the interests of Ohio public policy. Indeed, only six years ago this Court declined to allow a discretionary appeal in *Dean*, where the plaintiff, like McGowan in this case, complained the First District’s application of the clarity element was too narrow and at odds with Ohio law. *Dean v. Consol. Equities Realty #3, L.L.C.*, 123 Ohio St.3d 1424, 2009-Ohio-5340, 914 N.E.2d 1064 (denying *certiorari*).

The First District’s sound reasoning in *Hale* and *Dean* has been cited with approval and adopted by other courts applying Ohio law. For example, in *Crowley v. St. Rita’s Med. Ctr.*, 931 F. Supp.2d 824 (N.D. Ohio 2013), the plaintiff asserted a wrongful discharge claim against her former employer based on R.C. 1702.54, which prohibits the intentional falsification of public documents. Although the court acknowledged the statute serves an important public policy, it also noted “the statute does not impose a duty on employees to report violations of the statute, nor does it expressly provide protection for employees against retaliatory actions by the employer” *Id.* at 829. The court also recognized that decisions such as *Hale* and *Dean* are consistent with applicable precedent and with Ohio public policy while the plaintiff’s position represented “a new public policy exception to Ohio’s employment at-will doctrine,”— which is precisely the opposite of what McGowan argues in this case. *Id.* at 827. Consequently, the court granted summary judgment in favor of the defendant and, in the course of its opinion, held:

This Court finds more persuasive the reasoning of the Ohio courts that require the public policy invoked in a Greeley claim to parallel the policies underlying the whistleblower statute or protect employee or public safety. **The courts of Ohio generally have found that Greeley claims cannot lie with every public policy, even “good” ones, and appropriately so.** Without these limitations, Greeley claims could evolve from exceptions to the employment at-will doctrine to the rule itself. Here, **R.C. § 1702.54 neither requires reporting, nor protects against retaliation, nor protects employee or public health and safety. This statute represents a general prohibition against deliberate and deceitful falsification of corporate documents -- undoubtedly an important public policy, but not one that gives rise to a Greeley claim given the full weight of Ohio case law discussed above.**

(Emphasis added.) *Id.* at 831.

Another more recent, and equally well-reasoned, health care-related case reached the same conclusion. In *Hale v. Mercy Health Partners*, 20 F. Supp.3d 620 (S.D.Ohio 2014), the plaintiff based her wrongful discharge claim on, among other things, her complaints to the Drug Enforcement Agency (DEA) about certain of her employer’s record keeping practices which, she claimed, violated R.C. 2921.13(A)(7) and Ohio Adm. Code 4729-17-03.¹⁵ *Id.* at 639. After a thorough analysis of Ohio law, the district court, citing *Hale*, *Dean* and other Ohio precedent, granted summary judgment in the employer’s favor because the employee had failed to satisfy the clarity element of the *Greeley* test. In the course of its opinion the district court held:

Plaintiff has not established that the public policy is so manifestly clear to warrant abrogating the employment at-will doctrine. Plaintiff has not demonstrated that the administrative regulations parallel the whistleblower statute. The regulation does not require employees to report violations of the process set forth therein nor does it prohibit the facility from terminating an employee for such reports. Plaintiff also has not argued that she was terminated for reporting criminal violations or for reporting concerns relating to workplace or public health or safety.

¹⁵ R.C. 2921.13(A)(7) requires an individual to tell the truth when making a report to the government and Ohio Adm. Code 4729-17-03 requires pharmacies to maintain proper transport and record-keeping processes to ensure narcotics are properly accounted for. *Mercy Health Partners* at 637.

Id. The court went on to state that “[a]ccepting an argument that a clear public policy is established because an administrative regulation covers the subject matter at issue would expand the public policy claim to all statutory and administrative enactments. Under that view, the exception would swallow the rule.” *Id.*

McGowan also suggests, again incorrectly, this Court already has rejected the approach adopted by *Hale* and *Dean* that a source of public policy must “parallel” the reporting and retaliation provisions of the Ohio whistleblower statute (McGowan Merit Brief, p. 11). McGowan cites, for example, *Kulch v. Structural Fibers, Inc.*, 78 Ohio St.3d 134, 1997-Ohio-219, 677 N.E.2d 308 (1997), which held that the federal Occupational Safety and Health Act (“OSHA”) can provide the basis for a *Greeley* claim because the statute regulates “unsafe or unhealthy conditions in the workplace” and “specifically prohibits employers from retaliating against employees . . . who file OSHA complaints.” *Id.* at 151-53. McGowan claims *Kulch* went further and endorsed a law review article’s “rejection of the parallel approach.” In fact, *Kulch* does not even address the parallelism approach. It simply reaffirms the four criteria in *Greeley* and correctly concludes that a wrongful discharge claim based on a violation of OSHA satisfies those criteria. *Id.* Regardless, since the Court relied on the anti-retaliation provisions of OSHA which parallel the Ohio whistleblower statute, its decision is not a rejection of the “parallel approach” but a tacit endorsement of it. *Id.*

The First District’s decision is consistent with two other decisions of this Court which preceded *Kulch* and on which McGowan also relies: *Painter v. Graley*, 70 Ohio St.3d 377, 1994-Ohio-334, 639 N.E.2d 51 (1994), and *Collins v. Rizkana*, 73 Ohio St.3d 65, 1995-Ohio-135, 652 N.E.2d 653 (1995). In *Painter*, this Court affirmed the *dismissal* of the employee’s wrongful termination claim “[b]ecause there is no clear public policy in support of allowing public

employees to become candidates for partisan elective office.” *Painter* at 385. The plaintiff did not cite to any policy that explicitly protected an employee running for a partisan elected office from retaliation or that protected public health and safety. *Id.* The First District’s Opinion is, therefore, consistent with *Painter*.

In *Collins*, this Court recognized a wrongful termination in violation of public policy claim based on R.C. 2907.06, which “expresses a public policy protecting sexual bodily security and integrity and prohibiting offensive sexual contact.” *Collins* at 70. This Court also relied on R.C. 2907.21 *et seq.* which “prohibit prostitution, as well as compelling, promoting, procuring and soliciting prostitution.” *Id.* Clearly, those criminal statutes regulate and protect public health and safety and, therefore, the First District’s Opinion also is consistent with *Collins*.

C. Other Cases Cited By McGowan Also Do Not Support Her Claims

McGowan cites a string of other cases which she argues support her position that *Hale* and *Dean* were wrongly decided and that, therefore, the First District’s Opinion in this case should be reversed.

McGowan cites first to *Sabo v. Schott*, 70 Ohio St.3d 527, 639 N.E.2d 783 (1994), a case in which an employer allegedly terminated one of its employees who refused to commit perjury at the employer’s direction. *Sabo* is easily distinguishable from this case since Medpace never required, asked or expected McGowan to perform any illegal acts or engage in any other misconduct. To the contrary, as McGowan admitted at trial, Troendle explicitly encouraged her, if she saw fit, to change Stein’s prescription writing, and record keeping, practices however she wanted. (Tr. 858:2-5). And, in fact, that is precisely what she did. (Tr. 857:20-858:5). Setting aside the established fact that Stein’s practices were not illegal, at no time did Medpace require, or even suggest, that McGowan adopt the same practices. (Tr. 458:16-23; 857:20-858:5). To the

contrary, Troendle affirmed to McGowan that she was free to run the CPU and MARC as she saw fit.

McGowan also cites *Zajc v. HyComp*, 172 Ohio App.3d 117, 2007-Ohio-2637, 873 N.E.2d 337 (8th Dist.), which recognized a wrongful termination claim in violation of public policy where the plaintiff relied on statutes which prohibited the sale of defective, dangerous products. *Id.* at ¶¶ 25-26. McGowan cites *Zajc* for the proposition that a wrongful discharge tort is not limited to situations in which the discharge violates a statute. Though that premise demonstrates the danger of an ever widening exception to the employment at-will rule, the fact of the matter is that *Zajc* is consistent with the First District's Opinion because the policy upon which the employee relied was designed to protect public health and safety.

McGowan cites to other appellate cases for the proposition, with which Medpace agrees, that Ohio courts recognize wrongful termination claims based on alleged violations of criminal statutes and regulations. (McGowan Merit Brief, pp. 12-14). However, those cases all involve criminal statutes that regulate public health and safety – not statutes which deal with alleged fraud. See *McJennett v. Lake Waynoka Prop. Owners*, 12th Dist. Brown No. CA2013-05-006, 2013-Ohio-5767, ¶ 15 (“[C]lear public policy exists to encourage law enforcement officials to investigate and report crimes that occur at their workplace.”); *Bailey v. Priyanka Inc.*, 9th Dist. Summit No. 20437, 2001-Ohio-1410, *2-3, 10-12 (recognizing claim based on policy allowing for cooperation with police for prosecution of illegal narcotics); *Armstrong v. Trans-Service Logistics Inc.*, 5th Dist. Coshocton No. 04CA015, 2005-Ohio-2723, ¶ 3 (plaintiff satisfied clarity element based on FDA regulations which protect public food safety where employee was terminated for reporting meat that was transported at too high a temperature); *Avery v. Joint Twp. Dist. Mem'l Hosp.*, 286 Fed. Appx. 256 (6th Cir.2008) (wrongful termination claim based on

public policy against the falsification of medical records based, in part, on Ohio Adm. Code 4723-4-06(G) which specifically is designed to protect patient safety); *McKnight v. Goodwill Industries of Akron, Inc.*, 8th Dist. Cuyahoga No. 75973, 2000 Ohio App. LEXIS 2014 (May 11, 2011) (wrongful termination claim based on threats of physical violence by coworker in violation of criminal statutes). Again, none of these cases support McGowan's position since neither of the statutes on which she relies involve the protection of public health and safety.

The cases cited by McGowan do, however, highlight the dramatic and, for Ohio employers, devastating change to Ohio law which would result from a ruling in her favor. As the First District recognized, if every state and federal statute and regulation, however obscure or tangential to the employer's conduct, can be seized upon to support a wrongful discharge claim, then the important public policy behind Ohio's employment-at-will doctrine will, in fact, be destroyed. That is the ruinous consequence which courts such as *Dean, Hale, Crowley* and *Mercy Health Partners* refused to visit on Ohio employers but which McGowan nonetheless hopes to achieve in this case.

Appellant's Proposition of Law II: The Public Policies Manifested by R.C. 2913.47 and HIPAA Are Sufficiently Clear to Satisfy the Clarity Element of a *Greeley* Claim Under the Facts of This Case.

A. The Ohio Statute Relied on by McGowan is Inapplicable to Stein's Prescription Practices and to Medpace

McGowan's case suffers from another glaring, and fatal, flaw. There is no evidence in the record – because no such evidence exists – either that: (1) R.C. 2913.47 applies to Medpace in this case; or (2) Stein's ostensibly illegal actions should be imputed to Medpace. McGowan cited, for the first time at trial, Section 2913.47 (a criminal statute proscribing the submission of false insurance applications and false insurance claims) and Chapter 3901 (a civil statute which regulates insurance companies doing business in Ohio) in support of her personal opinion that

Stein's prescription writing practices constituted insurance fraud. She now has abandoned her reliance on Chapter 3901 and points solely to the equally unavailing Section 2913.47.

McGowan never claims that Medpace submitted a false insurance application, or made a false insurance claim, whether in connection with Stein's personal prescription writing practices or anything else. Medpace conducts clinical trials. It is not a health care provider, and its personnel do not write prescriptions in their capacity as Medpace employees. (Tr. 1253:13-24). McGowan does not dispute any of these facts. She does, however, continue to implicitly suggest in her brief that Stein's alleged shortcomings (which are in fact neither criminal or in violation of any public policy) somehow should be imputed to Medpace for purposes of this case. This conjured conflation of Stein's personal medical practice with Medpace's clinical research business may serve McGowan's purposes, but it is devoid of any factual foundation whatsoever.

Importantly, Ohio courts repeatedly have held that statutes which do not regulate the conduct of the employer cannot serve as the basis for a claim of wrongful discharge in violation of public policy. For example, in *McDonnell v. Cardiothoracic & Vascular Surgical Associates, Inc.*, S.D.Ohio, No. C2-03-0079, 2004 U.S. Dist. LEXIS 29439 at *28-30 (Aug. 3, 2004) the plaintiff based his wrongful discharge claim in violation of public policy on the defendant's alleged violation of the federal Stark Laws and Anti-Kick Back statutes. However, the trial court concluded those statutes could not be the source of the requisite public policy because, due to a statutory exception, the defendant was not subject to the provisions at issue. *Id.* at *30. Thus, the trial court dismissed the claim, as a matter of law, for lack of jeopardy. *Id.*

In *Dean*, the plaintiff based his wrongful termination claim on his former employer's alleged violation of an omnibus criminal anti-fraud statute, R.C. 2921.13. The First District dismissed the plaintiff's public policy claim and held that, as a matter of law, the anti-fraud

provisions in R.C. 2921.13 “would have made the customer’s alleged actions unlawful” if the customer made false statements inducing another to extend credit, but the statute did not regulate the conduct of the employer. *Dean*, 182 Ohio App.3d at 729, 2009-Ohio-2480, 914 N.E.2d 1109, at ¶ 12. The actions of a third party customer, whether improper or not, could not be imputed to the plaintiff’s employer. *Id.*

Taken to its logical conclusion, McGowan’s position in this regard would mean an employer could be subject to a wrongful discharge claim in violation of public policy because one of its employees complained to the employer about the alleged misconduct of an unrelated third party. As absurd as that sounds, that is the position which McGowan advocates in this case.

As discussed above, Ohio law also mandates, without exception, that an employee who alleges wrongful termination based upon Ohio public policy must articulate that public policy by citation to specific law. “A reviewing court may not *sua sponte* identify the source of that policy.” *Dohme*, 130 Ohio St.3d 168, 2011-Ohio-4609, 956 N.E.2d 825, at ¶ 23. McGowan never identified in her Complaint, in her motions and other filings in the trial court, or through her testimony at trial, any specific statute that supports her unsubstantiated claims that “pill-splitting” puts patients’ health at risk. Her insistence at trial that, for “safety’s” sake, a patient’s actual dose must match the prescription in the patient chart is strictly a matter of personal opinion and not supported by any state or federal statute, rule or regulation. McGowan also never established how her professed personal discomfort with pill-splitting constitutes insurance fraud. To the contrary, the uncontroverted evidence at trial indicated that even insurance companies endorse pill-splitting as a legitimate means by which to lower patient health care costs. McGowan simply never made, and still cannot make, any connection between pill-splitting and a violation any of provision of the Ohio Revised Code – because there is no connection.

In an analogous case, the Sixth Circuit Court of Appeals upheld the dismissal of a public policy claim based on an employee's reporting allegedly illegal and fraudulent conduct by officers of the corporation which employed him. *Hill v. Mr. Money Fin. Co. & First Citizens Banc Corp.*, 309 F.App'x 950, 965 (6th Cir.2009). Although the plaintiff cited several Ohio statutes that generally prohibit fraudulent behavior, he failed to identify specific language in those statutes that set forth a public policy that would be jeopardized by his termination. As the Sixth Circuit explained:

Hill asserts the existence of another clear public policy "prohibiting dismissal of bank employees in retaliation for reporting unlawful conduct by the officers of financial institutions," but does not clearly identify which specific "state or federal constitution, statute or administrative regulation" manifests that policy. Hill lists a number of state and federal laws that he characterizes as "sources of public policy" - namely, "the Ohio Mortgage Loan Act, 18 U.S.C. §656 (Theft, Embezzlement, or Misapplication by bank employee), 18 U.S.C. §1005 (Fraud and False Statements), 18 U.S.C. §1344 (Mail Fraud-Bank Fraud), 18 U.S.C. §1342 (Mail Fraud - Fictitious Name or Address)," the Ohio Whistleblower Statute, and the Federal Whistleblower Statutes. However, Hill does not match the "source" to the clear policy: we are left guessing as to which of these numerous statutes manifests a clear public policy against the "dismissal of bank employees in retaliation for reporting unlawful conduct by the officers of financial institutions," let alone what specific statutory language expresses said policy clearly. Even if such a policy were clearly manifest, this claim fails for the same reasons as above - there was no "reporting" of violations to external authorities. Since Hill did not establish the clarity element of the tort, whether he has established the jeopardy element is moot. For these reasons, we affirm the district court's dismissal of Hill's wrongful discharge claim in violation of Ohio public policy.

Id.

McGowan's personal opinions (which changed throughout this case), and shot-gun approach to the Ohio Revised Code, are no substitute for specific legislative authority directly on point required by *Hill* and many of the other cases on which Medpace relies. McGowan has utterly failed to establish the clarity element with respect to her fraud claims.

McGowan also has failed to establish the jeopardy element of *Greeley* with respect to this aspect of her claim and wholly failed to show she had a good faith belief that a violation of a particular statute occurred. *Pytlinski v. Brocar Prods.*, 94 Ohio St.3d 77, 2002-Ohio-66, 760 N.E.2d 385 (2002). A plain reading of R.C. 2913.47, first cited by McGowan at trial, and notably not cited in her Complaint, quickly confirms it does not apply to Medpace in any way. McGowan's after-the-fact reliance on R.C. 2913.47 cannot possibly support her contention that she had a good faith belief that Medpace had violated that statute when it terminated her employment for insubordination.

McGowan also made no attempt to properly "report" her concerns about Stein to any appropriate authorities outside Medpace. She never reported him to any professional organization, or any governmental body, or ask the Ohio Pharmacy Board to investigate her claims. *See Herlik v. Cont'l Airlines, Inc.*, 6th Cir. No. 04-3790, 2005 U.S. App. LEXIS 21784, *14-15 (Oct. 4, 2005) (dismissing public policy claim where plaintiff did not report safety concerns and "did not take any safety-related actions other than disagreeing" with an employee regarding alleged safety issues); *McDermott v. Cont'l Airlines, Inc.*, 339 F.App'x 552, 556-57 (6th Cir.2009) (affirming dismissal of public policy claim where plaintiff "made no report of Heckler's wrongdoing, and Avery's statements could be seen by the Hospital as a defense of her performance and not as a report of the violation of a government policy."). Similarly, McGowan's belated and calculated construct of a public policy claim cannot support her claim for wrongful discharge.

McGowan did not, and cannot, establish either the clarity element or the jeopardy element, as to Medpace; therefore, the trial court should have dismissed her wrongful discharge claim as a matter of law and this Court should affirm the First District Court of Appeals.

B. McGowan Cannot Satisfy the Clarity Element or Jeopardy Element with Respect to Alleged HIPAA Violations

1. McGowan Cannot Rely on C.F.R. 160.316, Which Also Is Inapplicable to Her Claims

In her brief, McGowan alleges, **for the first time in this entire case**, that HIPAA includes anti-retaliation provisions which satisfy the requirements articulated by the First District. The provisions on which McGowan relies are not in the statute itself, but rather are set forth in the Code of Federal Regulations and promulgated pursuant to HIPAA's privacy rule. *See* 45 C.F.R. 160.316. First, as a threshold proposition, it is black-letter law that this argument – which McGowan never raised in the trial court or in the First District – cannot be advanced for the first time before this Court. *Shover v. Cordis Corp.*, 61 Ohio St.3d 213, 218, 574 N.E.2d 457 (1991) (“It is axiomatic, however, that issues not presented for consideration below will not be considered by this court on appeal.”) (citations omitted) (overruled on other grounds). McGowan's prior general references to HIPAA do not excuse this omission since, again, this Court's controlling precedent compelled her to cite to, long before now, specific legislation or regulatory authority. *See Dohme*. Second, 45 C.F.R. 160.316(c), on its face, does not apply to McGowan's claims. The combination of patient charts – particularly with the patient's consent - is not unlawful under HIPAA. And the manner in which McGowan complained, by slandering Stein in the presence of Medpace staff members, was not reasonable, as the regulation requires. *Id.* Accordingly, this Court should decline to afford McGowan's newfound reliance on 45 C.F.R. 160.316 any consideration.

2. HIPAA Does Not Embody the Type of Public Policy Contemplated by *Greeley*

HIPAA is designed to regulate patient privacy in the medical industry. 42 U.S.C. 1320d. The statute: (1) does not place an affirmative duty on the employee, separate from the

whistleblower statute, to report any HIPAA violation, (2) does not specifically prohibit the employer from retaliation, and (3) is not intended to protect the public's health and safety. As such, and as the First District properly held, "HIPAA manifests an important and useful public policy, but the protection of patient privacy is not the type of public policy contemplated by *Hale* or *Dean*." *Medpace*, 2015-Ohio-3743, 42 N.E.3d 256, at ¶ 26.

McGowan argues *Wallace v. Mantych Metalworking*, 189 Ohio App.3d 25, 2010-Ohio-3765, 937 N.E.2d 177 (2d Dist. 2010), otherwise supports her position. In that case the Second Appellate District did not conduct any type of analysis of the evolution or current status of the public policy exception to Ohio's employment-at-will doctrine. It simply found that protecting the confidentiality of medical records is a public policy (which is true) and then, without any further discussion, considered the impact of HIPAA in connection with its review of the plaintiff's wrongful discharge claim. *Id.* at ¶ 42. Notably, in the end the Court of Appeals affirmed the trial court's summary judgment in favor of the employer because, as is the case here, there was no evidence the employer had violated HIPAA. *Id.* at ¶¶ 45-46.¹⁶

Furthermore, this Court has held that "an exception to the traditional doctrine of employment at-will should be recognized only where the public policy alleged to have been violated is of equally serious import as the violation of a statute." *Painter*, 70 Ohio St.3d at 384.

¹⁶ The OELA cites *Rebello v. Lender Processing Services, Inc.*, 8th Dist. Cuyahoga No. 101764, 2015-Ohio-1380, 30 N.E.3d 999, another case that did not engage in any analysis of the evolution or current state of the public policy exception to Ohio's employment-at-will doctrine, or discuss the wisdom of expanding that limited exception. The case also involved a consumer protection statute, not HIPAA.

The OELA also cites *Anders v. Specialty Chem. Resources, Inc.*, 121 Ohio App.3d 348, 700 N.E.2d 39 (8th Dist.1977), another Eighth District case, in support of McGowan's claim that Medpace terminated her employment for complaining about the manner in which Stein combined the charts of certain CTC and MARC charts. However, this case also has nothing to do with HIPAA since the employee was fired for refusing to inflate damage claims resulting from a fire at his employer's facility.

McGowan's belated reliance on a little used regulation¹⁷ promulgated under HIPAA, which she did not even identify until her appeal to this Court, cannot satisfy that test.

Finally, McGowan's reliance on 45 C.F.R. 160.316 is futile in any event since its provisions expressly state that it is applicable only "provided the individual or person has a *good faith belief* that the practice opposed is unlawful, and the manner or opposition is reasonable and does not involve a disclosure of protected health information. . . ." 45 C.F.R. 160.316. As discussed in more detail below, McGowan cannot demonstrate the good faith belief mandated by this provision.

3. McGowan Did Not Have a Good Faith Belief that HIPAA was Violated and HIPAA was Not Jeopardized by Plaintiff's Termination

At the outset it is important to note that the audits which the FDA and the study sponsors regularly performed at MARC (and the CPU) included a thorough review of patient charts. (Tr. 860:1-861:5). MARC always passed those audits with flying colors and never once did the FDA or any sponsor identify any possible HIPAA infractions or otherwise question the manner in which MARC maintained those charts. Troendle testified that:

I know FDA always complimented on how thoroughly it's done, our charts, and how easy it is to find the information in the charts. We've never had any – any concerns raised against the charts.

(Tr. 1199:5-9). It also is important to distinguish the HIPAA concerns which McGowan tactically raised only after she filed suit and those she actually voiced prior to her termination.

After she filed suit, McGowan complained about the possible "*exposure*" of patient charts (by Stein, not Medpace) that were placed just outside of the examination rooms, while the patient waited for the treating physician to arrive. According to McGowan, she was concerned

¹⁷ According to a LEXIS search, 45 C.F.R. 160.316 has been cited just seven times over the past ten years since the law's enactment.

that other patients being escorted to a nearby examination rooms would be able to glance at the charts as they passed by (Tr. 342:6-19). There is, however, no allegation that Stein – let alone Medpace – ever shared a patient’s medical information with any unauthorized individual. In fact, the same Privacy Rule regulations McGowan now points to expressly recognize and protect incidental uses and disclosures (45 C.F.R. 164.502(a)(1)(ii)) as long as the health care entity has implemented reasonable safeguards to protect the patient’s privacy. *Id.* As a physician, McGowan presumably knew of these Privacy Rule exceptions. In any event, McGowan never has alleged, and there is no evidence in the record, that she ever reported these particular concerns to Troendle, Nolen, or Khodadad in her meeting with them on July 27 or at any time. Indeed her own notes of the meeting, which she described as “completely accurate,” contain absolutely no mention of this issue. (Tr. 408:23-409:17 and McGowan Ex. 43). Consequently, this issue merits no consideration, as Medpace could not possibly have retaliated against McGowan based on a complaint she never raised prior to her termination of employment.

McGowan did raise concerns before her termination about the *combination* of certain CTC patient charts and the MARC study files (again, by Stein, not Medpace) for those same patients. McGowan quickly discovered, however, that all of Stein’s patients had signed consent forms by which they agreed their medical charts and clinical trial study charts could be combined. (Tr. 497:2-498:15). In particular, Medpace’s Quality Assurance Director, Chris Ernst informed McGowan – long before her termination – that Stein had complied with HIPAA because his patients each had signed forms consenting to this practice. (Tr. 497:2-498:15 and Medpace Ex. 115). He also reminded her that under the circumstances the *failure* to combine the files, or otherwise provide MARC with access to the patient’s medical history, could create regulatory compliance problems:

Per GCP, we have to permit review of all medical records, which the consent also allows and, therefore it, is provided/viewed. However, the HIPAA consent is an agreement between the patient and PI and, ultimately, the PI's responsible to control access of those records within the facility.

...

However, if you feel that a separate personal file is warranted this could be created, realize, however, this could be kept from a sponsor or CRA, but the FDA would require access to it if they are aware of it, or we could be cited with a refusal to grant access, which has very serious regulatory implications.

(Tr. 497: 10-25 and Ex. 122).

Where an exception like this exists, the actions of the defendant are legal, and jeopardy is eliminated. *McDonnell*, 2004 U.S. Dist. LEXIS 29439 at *28-30. Moreover, McGowan's initial reactions – which promptly were put to rest by Chris Ernst – cannot form the basis of her public policy claim where she disagreed with, or simply chose to ignore, the legal exception on which Stein properly relied. *Crowley*, 931 F. Supp.2d at 832-833 (finding jeopardy element not met because “[i]t cannot be that the jeopardy element would be satisfied any time an employee disagrees with her employer and invokes public policy.”).

Any possible debate about McGowan's demonstrable lack of good faith is ended by the fact that on February 25, 2015 a federal district court jury in Cincinnati found McGowan guilty of slander and awarded Stein substantial compensatory and punitive damages, plus his attorneys' fees. McGowan cannot seriously argue that she satisfied the good faith tenet of the jeopardy element of *Greeley* when it already has been determined by a jury of her peers that she acted, not in good faith at all, but in a reckless and vindictive manner. For this Court to reverse the First District, and thereby reward McGowan for her slanderous statements, would be both irreconcilable with the jury's verdict and a monumental injustice.

4. McGowan Also Cannot Establish the Jeopardy Requirement Because the Public Interest is Otherwise Adequately Protected

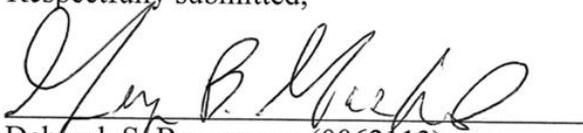
To satisfy the jeopardy element, a court also must inquire “into the existence of any alternative means of promoting the particular public policy to be vindicated by a common-law-wrongful-discharge claim.” *Wiles*, 96 Ohio St.3d 240, 2002-Ohio-3994, 773 N.E.2d 526, at ¶ 15. In *Wiles*, this Court determined that “allowing a wrongful discharge claim based on the policy expressed in the Family and Medical Leave Act (“FMLA”) was unnecessary to vindicate the policy goals of the FMLA.” *Leininger v. Pioneer Nat’l. Latex*, 115 Ohio St.3d 311, 2007-Ohio-4921, 875 N.E.2d 36, ¶ 26 quoting *Wiles*. In other words, there is no need to recognize a common law action for wrongful discharge if there already exists a statutory remedy that adequately protects society’s interests by discouraging the wrongful conduct. *Leininger* at ¶¶ 26-27, quoting *Wiles*. Therefore, to satisfy the jeopardy element, McGowan also must demonstrate that without a common law tort claim for wrongful discharge, the public policies advanced by HIPAA would be compromised.

Here, the entire statutory scheme of HIPAA is designed to protect and enforce the confidentiality of patient health care information. Under 42 U.S.C. 1320d-5, the Department of Labor can impose fines of up to \$50,000 per violation (subject to an annual maximum fine of \$1.5 million). The statute also subjects violators to imprisonment for up to ten years. Given these harsh sanctions it is unnecessary, and unwarranted, to create another public policy exception to the employment-at-will doctrine to protect the public’s interest in discouraging violations of HIPAA.

IV. CONCLUSION

For the foregoing reasons, Medpace, Inc. hereby requests that this Court reject McGowan’s efforts to expand the exceptions to the employment-at-will doctrine, and affirm the judgment of the First District Court of Appeals.

Respectfully submitted,



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CERTIFICATE OF SERVICE

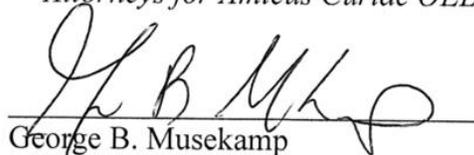
I hereby certify that a copy of the foregoing has been served upon the following this 15th day of June, 2016 via ordinary U.S. mail, postage prepaid:

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