

June 2, 2009

Elisabeth A. Shumaker
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

WADE PEDIATRICS,

Petitioner,

v.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES, CENTERS FOR
MEDICARE AND MEDICAID
SERVICES,

Respondent.

No. 08-9529

**Petition for Review from the Departmental Appeals Board
of the Department of Health and Human Services
App. Div. Docket No. A-08-06
Decision No. 2153**

Sarah J. Glick, Scoggins & Cross, PLLC, Oklahoma City, OK (Linda G. Scoggins with her on the briefs), for Petitioner.

G. Dirk Rozendale, Assistant Regional Counsel, Department of Health and Human Services, Dallas, Texas (Thomas R. Barker, Acting General Counsel, and Katherine W. Brown, Acting Chief Counsel, with him on the brief), for Respondent.

Before **LUCERO, O'BRIEN**, and **GORSUCH**, Circuit Judges.

GORSUCH, Circuit Judge.

From time to time, labs federally certified to analyze human specimens must take proficiency tests to ensure their reliability and accuracy. On two such tests, Wade Pediatrics checked its answers with those of another lab before submitting its results to the government. The problem is that the government's proficiency testing program seeks to assess the competency of each lab's independent work. Sharing answers defeats the purpose of the exercise. Even more pointedly, sharing answers violates the clear and unambiguous terms of a federal statute. In response to Wade's statutory violation, the government suspended its certificate for one year. We deny Wade's petition for review of that decision.

I

Labs like Wade must meet certain federal standards in order to be certified to conduct diagnostic tests on human specimens (blood, tissue, and the like), and to receive Medicare or Medicaid reimbursement for their services. These standards are embodied in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA" or "the Act") and its implementing regulations. *See* 42 U.S.C. § 263(a); 42 C.F.R. Part 493. Among other things, certified labs must participate in periodic quality control proficiency tests.

Wade's troubles began in 2005 when it flunked portions of two proficiency tests. In response, a field investigator for the Centers for Medicare and Medicaid Services ("CMS") advised Wade "that it would be beneficial" for the lab "to

receive training and comparison testing of the[ir] equipment from another” certified lab, such as the nearby Muskogee Regional Medical Center. Wade followed up on this recommendation, arranging to receive training and technical support from Muskogee.

In February 2006, Wade took another proficiency test. This time, instead of testing the proficiency testing samples in Wade’s own lab, a technician first took the samples to Muskogee and tested them on Muskogee’s equipment. Only then did the technician return the samples to Wade’s lab and run tests on them there. The purpose of all this was apparently to double-check Wade’s results to ensure their accuracy before submitting anything to the government.

As yet unaware of Wade’s conduct in connection with the February 2006 proficiency test, in March 2006 the government notified Wade that it was temporarily restricting the scope of its certificate based on its 2005 problems. In due course, Wade submitted a remedial plan to CMS promising to correct its errors and adding that, toward this end, it was already engaging in training and consultation with Muskogee’s staff. Wade added that it would “continue internal proficiency testing with assistance and support/guidance” from Muskogee. When CMS sent Wade yet another set of proficiency testing samples in May 2006, Wade again checked its test results against results achieved in Muskogee’s lab before submitting its answers to the government.

Eventually, CMS got wind that Wade had twice tested its proficiency testing samples at another lab before submitting its results. CMS responded by revoking Wade's certificate for one year, citing as authority for its actions 42 U.S.C. § 263a(i)(4), which provides that “[a]ny laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year. . . .” Wade unsuccessfully challenged the revocation of its certificate before an ALJ, and then before the Departmental Appeals Board (“DAB”) of the Department of Health and Human Services.

Failing to obtain relief in the administrative context, Wade petitions to us. *See* 42 U.S.C. § 263a(k)(1). Wade asserts that its actions did not violate the CLIA, and, alternatively, that CMS should be estopped from revoking its certificate because it induced Wade into sharing its proficiency test results with Muskogee. We address each argument in turn.

II

Wade argues first that it did not “refer” its proficiency testing samples “for analysis” to Muskogee in violation of § 263a(i)(4) of the CLIA. In Wade's view, the Act prohibits a lab only from passing off another lab's results as its own work; it does not prohibit a lab from double-checking its own results with another lab. And, Wade stresses, it corresponded with Muskogee not out of any design to

cheat the proficiency testing program but simply as part of a training program, undertaken in good faith, to confirm the accuracy of its own work.

Even accepting Wade's description of its actions, they still violated the plain and unambiguous terms of the statute. To "refer" means "to commit, submit, hand over (a question, cause, or matter) to some special or ultimate authority for consideration, decision, execution. . . ." Oxford English Dictionary, Vol. XIII at 463 (2d. ed. 1989). "Analysis," in turn, means "[t]he resolution or breaking up of anything complex into its various simple elements . . . ; the exact determination of the elements or components of anything complex (with or without their physical separation)." *Id.* Vol. I at 433. Without doubt, Wade committed, submitted, or handed over for consideration its proficiency testing samples to Muskogee for analysis – that is, for Muskogee's resolution or breaking up of those samples into their various simple elements. Of course, as it contends, Wade did not simply pass off Muskogee's results as its own. But nothing in the text of § 263a(i)(4) suggests that a test-taker must pass off another lab's results before a violation has occurred. Under the statute's plain terms, *any* intentional "referral" of a proficiency testing sample "for analysis" in another lab is forbidden. And that indubitably occurred here.

Wade is like the student who protests that he did not cheat on his exam because he did not hand in someone else's work but merely checked his answers against those of another student. But peering over the shoulder of another student

in the middle of an exam to check one's answers is as much cheating as handing in someone else's work. While consultation between labs may be permissible in other circumstances, before or after a proficiency test, asking an outsider for help during a test corrupts the process and defeats its purpose. Indeed, this type of double-checking is exactly what Congress sought to prevent in the CLIA. It is not just passing off another's work as one's own that concerned Congress:

“Run[ning] repeated tests on the sample, us[ing] more highly qualified personnel than are routinely used for testing, or send[ing] the sample out to another laboratory” are all among the many practices that “obviously undermine the purpose of proficiency testing.” H.R. Rep. No. 100-899, at 16, 24 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3828.

Even if it did “refer” its test samples “for analysis” to Muskogee, Wade replies that it did not do so “intentionally,” as the statute requires before CMS may impose a one-year suspension. Although Wade agrees with CMS that the statutory term “intentional” connotes “knowing and willful,” Aplt. Br. at 10, Wade stresses that it had no wish to violate the law, and in fact was seeking to do just the opposite – to improve its testing standards by reaching out to another lab for guidance.

This line of argument will not work either. Even assuming Wade's *ultimate* or *end* intent was to improve its work product, as a *means* of effecting that intent Wade surely referred its proficiency test results “knowingly and willfully” to

Muskogee. Wade does not suggest, for example, that its technician negligently left the lab's proficiency testing samples at Muskogee and Muskogee went ahead, without Wade's knowledge, to analyze them. Instead, it is undisputed that Wade's technician took the lab's proficiency testing samples to Muskogee with the express purpose of testing them there – that is, with the express purpose of referring them for analysis. There was no mistake, accident, negligence or recklessness about it. And under the statute's plain language, such a “knowing and willful” action is sufficient to trigger liability, even if it was undertaken only in service of some further and ultimate intent. Simply put, Wade is responsible for its intended *means*, whatever its intended *ends* might have been.

CMS makes much the same point when it maintains that Wade's “motive” in asking Muskogee to analyze its test samples is “irrelevant.” Appellee Br. at 17. While Wade might well have acted with the benign motive of seeking to improve its testing standards, CMS argues, that is neither here nor there; the statute asks only whether a lab has acted intentionally. CMS's argument recalls the oft-repeated maxim every law student hears that the law cares about intent, not motive. But like many maxims, this one obscures difficult analytical questions – in this case, the longstanding question what qualifies as a motive rather than an intention. *See, e.g.,* Wayne LaFare, Substantive Criminal Law § 5.3(a) (2008) (“[W]hat is meant by the word ‘motive’ and how it differs from ‘intention,’ [is] a matter which has caused the theorists considerable difficulty for

years.”); Walter Cook, Act, Intention and Motive in the Criminal Law, 26 Yale L. J. 624 (1917); Walter Hitchler, Motive as an Essential Element of Crime, 35 Dick. L. Rev. 105 (1931). But whether Wade’s state of mind is characterized as a motive, as the government would have it, or as a further intent, as Wade would have it, makes no difference to the outcome of this case. However characterized, the fact that Wade acted with the earnest desire to improve its testing standards does not negate the fact that the company *did* intentionally refer its proficiency testing samples to another lab for analysis.

III

Perhaps seeing the writing on the wall, Wade supplements its statutory argument with another approach. Even if it violated the statute, Wade submits, it did so only at the direction and with the approval of CMS. Wade points to the 2005 statement by the CMS field investigator urging Wade to seek out opportunities for “training and comparison testing of the[ir] equipment” with other certified labs. Wade also points to the remedial plan it submitted to CMS where it made mention of its correspondence with Muskogee. Because CMS urged or at least tacitly approved its cooperation with other labs, Wade maintains, the government should be estopped from complaining that it did just that. The DAB of course disagreed with this line of argument, and we cannot say that its factual findings lack substantial evidence or that its legal rulings were erroneous.

To the contrary, winning an equitable estoppel argument against the government is a tough business. Courts generally invoke estoppel against the government “only when it does not frustrate the purpose of the statutes expressing the will of Congress or unduly undermine the enforcement of the public laws.” *FDIC v. Hulsey*, 22 F.3d 1472, 1489 (10th Cir. 1994). In addition to requiring the traditional elements of estoppel, we require the party claiming estoppel to show “affirmative misconduct on the part of the government”; mere “erroneous advice” will not do. *Id.* at 1489-90 (noting that traditional elements of estoppel are (1) the party to be estopped must have known the facts; (2) that party must have intended that its conduct would be acted on or must have acted such that the party asserting estoppel had a right to believe it was so intended; (3) the asserting party must have been ignorant of the true facts; and (4) the asserting party must have relied on the other party’s conduct to his injury); *see also INS v. Miranda*, 459 U.S. 14, 17–19 (1982); *Board of County Comm’rs of County of Adams v. Isaac*, 18 F.3d 1492, 1499 (10th Cir. 1994). Courts are parsimonious about estoppel claims against the government for good reason: “When the government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined.” *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 60 (1984). The public should not have to suffer, the reasoning goes, because of a bureaucratic bungle. *See Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414,

422 (1990) (noting that the Supreme Court had, to date, “reversed every finding of estoppel that [it had] reviewed”).

Wade does not come even close to meeting its burden under this standard. Wade stresses that a CMS representative suggested the lab work with another certified lab to train its employees and confirm the reliability of its equipment. But there’s no hint in the record that CMS erroneously advised Wade that it could or should share proficiency testing samples with another lab prior to handing in its own proficiency test results (let alone that CMS engaged in any affirmative act of misconduct). Teachers often allow students to work collaboratively to prepare for an exam or to discuss answers after an exam, but that is no license for students to share thoughts and answers during the exam. Under the statute, Wade might have been free to work with another lab to train its personnel and to fix its equipment, but it’s a very different thing to compare results during the testing process.

Wade replies by pointing to its remedial plan. There, Wade told CMS that it intended to “continue internal proficiency testing with assistance and support/guidance” from Muskogee. Even if one could read this statement as clearly notifying CMS of Wade’s intent to break the law – a debatable enough proposition – CMS said nothing in response. CMS did not condone or applaud Wade’s plan. Silence, of course, does not rise to the level of giving erroneous advice – which is still insufficient to warrant estoppel against the government –

let alone to the level of “affirmative misconduct” required to warrant estoppel against the government.

The petition for review is denied.