

Testimony of Rina Wolf
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Chairman Gonzalez, Congressman Westmoreland, Congressman Altmire and distinguished Members of the Subcommittee, good afternoon and thank you for inviting me here today to share with you my experience and challenges with Medicare regulations that are not keeping pace with, and hampering the evolution of medical technology and personalized medicine in the United States.

My name is Rina Wolf and I am the Vice President of Reimbursement and Regulatory Affairs for RedPath Integrated Pathology, Inc., a genomics-based cancer diagnostics company located in Pittsburgh, PA. RedPath was founded in 2004 as the realization of the dream of renowned pathologist, Dr. Sidney Finkelstein, who's lifework has been the development of a means to answer questions around cancer diagnoses that are unanswerable through previously available technologies.

Today, RedPath operates as a fully accredited laboratory, providing complex testing services that help oncologists and pathologists to resolve indeterminate cancer diagnoses and shape cancer treatment plans. Our test, *PathFinderTG*®, is based upon a powerful proprietary technology platform that was under development for 15 years prior to commercialization. It is clinically validated with strong peer review and support,

and is being used by clinicians in major cancer centers, including half of the major National Comprehensive Cancer Network (NCCN) Cancer Centers in the US.

PathFinderTG allows earlier and more informed diagnosis of cancers, such as pancreatic cancer - a cancer that has historically been very difficult to diagnose and very aggressive. When suspected, but not definitively diagnosed, physicians typically have two options: “watch and wait” to see whether in fact cancer develops over time, or remove major portions of the patient’s pancreas to definitively limit the spread of cancer. Neither is without serious consequence. Because of the aggressive nature of this cancer, waiting and thereby delaying treatment can have fatal results. However, removing major portions of the patient’s pancreas out of an abundance of caution also has grave implications, including significant surgical morbidity, as well as long-term consequences, such as leaving the patient with insulin-dependent diabetes. Moreover, 70 percent of patients undergoing radical pancreatic surgeries for certain types of tumor are found not to have pancreatic cancer.

By providing a definitive diagnosis, *PathFinderTG* provides information that can help to preserve the patient’s quality of life, while assisting physicians in selecting an appropriate, timely and cost-effective treatment plan. A recent study demonstrated that making a definitive diagnosis through *PathFinderTG* reduced the number of pancreatectomies on benign conditions by 34 percent.

RedPath is part of a small, but growing industry that is translating knowledge gained from the Human Genome Project into clinical practice by providing treatments that are tailored to individual patients based on their DNA and specific molecular character of their disease. By understanding the molecular nature of disease, new technologies increasingly allow clinicians and patients to pick individually appropriate treatment options, rather than basing treatment choices on broad assessments of what works best for a population. Personalized medicine has the potential to:

- Detect disease at an earlier stage, when it is easier to treat effectively;
- Enable the selection of optimal therapy and reduce trial-and-error prescribing;
- Reduce adverse drug reactions; and
- Increase patient compliance with therapy.

RedPath also is one of several new technologically-based companies providing job growth for Southwestern Pennsylvania as its economy shifts from manufacturing and service to a life science and robotics industry. A decade ago, only 1 or 2 life science companies were being created every year in southwestern Pennsylvania - which is amazing when one considers the research universities and world-class teaching hospitals located in the Commonwealth. Today, with RedPath and fellow biotechnology companies leading the way, 15-20 life science companies are being created each year in Southwest Pennsylvania.

In just 4 years, we have grown to 51 employees, and have expanded from 2,000 square feet to 20,000. And, as is the case with most life sciences companies, our workforce is

highly-educated and well-compensated. We're not just providing jobs, but better quality jobs to our region. We're also bringing venture capital money and investment dollars to the region from national funds that understand the promise of the diagnostics industry.

As you can imagine, ours is a highly regulated industry, and rightly so. Poor quality is not an option. Lives hang in the balance. It is important, in fact necessary, that federal and state authorities and non-governmental accreditation organizations provide rigorous oversight of our research, methodologies, processes and outcomes.

However, it is likewise necessary that all regulatory regimes keep pace with the rapidly evolving world of science and technology, and operate to promote innovation. Outdated regulations and calcified regulatory agencies can stifle innovation and prevent new life-saving diagnostics and therapies from ever coming to market. They can also serve as a drag on our economy.

RedPath and similarly situated specialty laboratories are currently struggling to cope with a Medicare regulation that is threatening our very viability and patient access to *PathFinderTG*.

Medicare has two regulations that together operate to stymie access to these life-saving diagnostics. First, Medicare's "date of service" regulation (42 C.F.R. § 414.510) generally provides that any test furnished within 14 days after the patient's discharge from a hospital is deemed to have been performed on the day the specimen was

collected, for example, when the blood was drawn or tissue biopsied. In other words, the date of service will be when the patient was in or at the hospital. Intuitively, this rule makes no sense given that the *PathFinderTG* and other specialized laboratory tests are typically performed and reported to the treating physician after the patient has left the hospital, and the results are used for management of the patient following discharge from the hospital, and bear no relationship to the services furnished to the patient during the hospital stay.

Under separate Medicare rules (42 C.F.R. §§ 411.14(m) and 410.42), hospitals are obliged to assume professional and financial responsibility for tests furnished during a patient's hospital stay. The combination of these rules creates a host of financial and administrative problems and disincentives for hospitals to allow access to our technology. For example, Medicare's bundling rules require hospitals to exercise professional responsibility over all services they provide, even those for which they contract. Hospitals are unwilling to assume professional responsibility for tests like ours that are not offered by the hospital, and which are, in fact, offered by laboratories that are completely unfamiliar to the hospital, and may not even be ordered by a physician affiliated with that hospital. In one common scenario, a hospital may physically possess a patient specimen as a result of a procedure that was performed at that hospital. The patient decides to have a consult at a completely different institution. The second institution makes the determination that a *PathFinderTG* is medically necessary. As a courtesy, the first hospital will forward the specimen to RedPath for testing. Because of Medicare's rules, the first hospital is now professionally responsible for the test, even

though it had nothing to do with ordering the test, does not furnish the test, and does not see the results.

Additionally, hospitals also have financial reasons to block these tests. Because Medicare requires that the hospital bill for services furnished during the hospital stay (even when the services technically are not furnished during the hospital stay, but are related back to the hospital stay by the date of service rule), the hospital must assume the financial risk that the service is covered and that Medicare will pay for it, or, in those instances where a specimen was collected as part of an in-patient stay, absorb the cost of these tests as part of their Medicare DRG payment.

In light of these and other administrative and financial disincentives, hospitals are encouraging physicians to delay ordering the tests until after the 14 days; others are cancelling orders altogether. Imagine, if you will, that you or someone you love is faced with a suspicion of pancreatic cancer. After the biopsy, it usually takes two to three days for a traditional pathology analysis to determine whether cancer is present. If that analysis were inconclusive, and a need for *PathFinderTG* testing was indicated and subsequently ordered by the patient's treating physician, the hospital may seek to delay sending the specimen to RedPath for two weeks until the 14-day time period lapses. From the time RedPath receives the specimen, it typically takes another five days to get a result. Consequently, three to four weeks pass before the patient receives a diagnosis of whether cancer is present. Besides the tremendous anxiety while waiting for this answer, if there was a diagnosis of a malignancy, the additional time before

treatment or surgery could affect the outcome. Physicians and patients are faced with an untenable choice: order the test when it is clinically appropriate, or artificially delay ordering the test (and initiating therapy) until such time as the specialty laboratory can accept full responsibility for its service and liability for Medicare's reimbursement. This leaves the patient and physician in limbo at a time when each passing day can have clinical consequences, and when they are desperate to make critical treatment decisions to determine if there is cancer and, if so, arrest the spread of cancer.

In January 2008 alone, 66-percent of specimens for Medicare beneficiaries that would have been the hospitals' responsibility to bill were cancelled when the hospitals learned they were responsible for furnishing the test under arrangements.

CMS almost certainly did not intend for Medicare's date of service rule to restrict access to specialized *in vitro* diagnostic tests as it is. Nonetheless, the rule remains in place. RedPath and other similarly situated laboratories, as well as the American Clinical Laboratory Association, have met with CMS, including the agency's senior leadership, on numerous occasions about this issue. We appreciate the agency's willingness to meet with us and review these serious issues; we remain hopeful that CMS will propose a new remedy for this problem in the forthcoming update to Medicare's physician fee schedule this summer. It is completely within CMS's authority to make the necessary change.

It is important that payors, especially public payors, establish reimbursement policies that enable them to be good stewards of public funds. However, it is more important that these policies take a broad view, and not be pound foolish to be penny wise. The federal government should be a prudent purchaser of healthcare items and services, but also enable patient access to new technologies, especially those that can ultimately save patients and taxpayers money – for example, by avoiding unnecessary and expensive surgeries. Federal health care agencies also should seek to promote technological innovation and support companies that are vital economic engines.

I applaud this Subcommittee for studying and focusing attention on this important area, and implore CMS to remove this impediment to the promise of personalized medicine. Again, thank you for inviting me here today and for listening to my statement. I would be delighted to take questions.