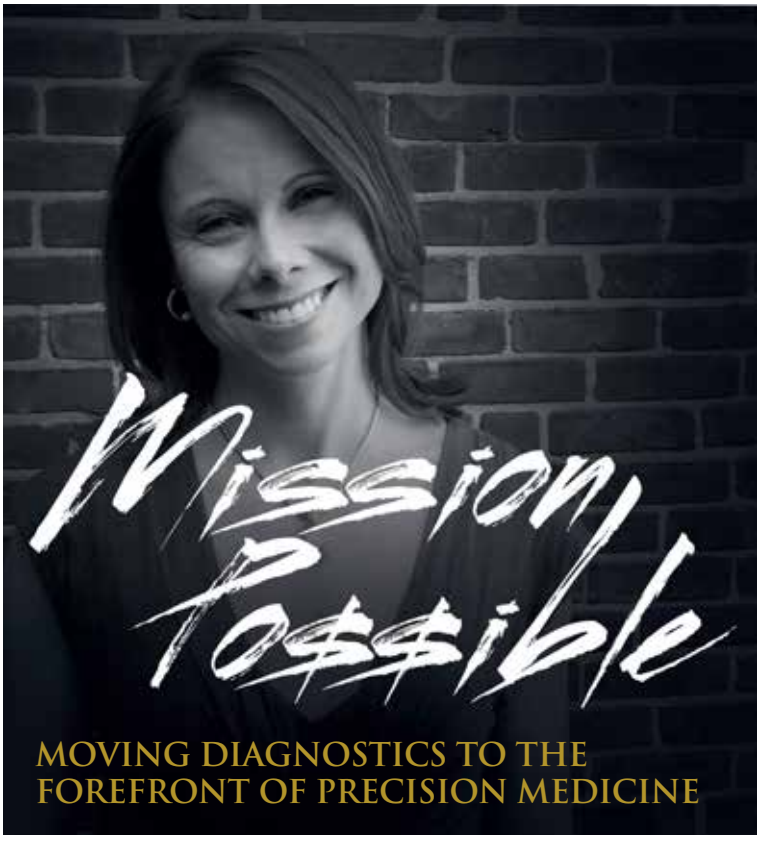

WHY DIAGNOSTICS HAVE TROUBLE FINDING THEIR VOICE

by Hannah Mamuszka

In recent years, as healthcare costs and efficiency has been a topic of nearly constant debate in the United States, many stakeholders have amplified their voice. Rising costs and significant disparities in care are a universal source of concern for everyone.

There has been a myriad of solutions proposed to help stem the rising tide, most of which shift burden from one group to another, without clear benefit to the patient or larger group outcomes. Some recent proposals, such as matching drug prices in the US to negotiated drug prices in other countries, seem unlikely to happen as they are tied to many other factors not relevant to the United States. Others, such as moving away from fee-for-service patients and tying physician payment to patient outcomes, are more realistic, but challenging to implement in the real world which has been reticent to change.

Increasing costs for many medical services, necessitated by our growing, aging, and relative to other countries, sick population, are the driving factor. Confounding factors include the number of people with chronic diseases, increased costs for outpatient and emergency room care, and higher premiums and out-of-pocket costs. The costs of specialty drugs continues to rise, as does the cost of older and generic medications like insulin. Recent achievements by the pharmaceutical industry in developing completely novel therapies for rare diseases have been (and will be) life saving and life changing in diseases like Spinal Muscular Atrophy, cancer, hemophilia and others- at a steep price. Combined together and the US spends 2.5 times as much per capita as the United Kingdom, with poorer outcomes and shorter life expectancy.

We hear a lot of the same voices we hear over and over. As of this writing, several pharmaceutical executives are scheduled to testify before Congress in the coming weeks, to justify the rising costs of therapies that are magnitudes higher in the US than in other countries. Through their lobby group PhRMA, the pharmaceutical industry, tired of being blamed for rising costs and feeling that they are not getting credit for innovation, has launched a series of commercials intended to inspire and bring hope to patients suffering from illness, as well as remind everyone that sometimes the high prices are worth it. According to the non-partisan Center for Responsive Politics, pharmaceutical companies spent $900 million on lobbying between 1998 and 2005, more than any other industry- and they have only increased their spending in recent years. No doubt- pharma is loud in healthcare, has lots of money, and inspires passionate debate- lifesaving drugs vs exorbitant prices.

Physicians have prominent voices too. While the American Medical Association (AMA) may not speak for all physicians, the AMA is one of the most powerful lobby groups in the US. The AMA threw its powerful support behind at Affordable Care Act (ACA), arguing for increased coverage and care for all Americans, and has equally powerfully resisted changes in the standard fee-for-service based pricing that pays physicians and hospitals for the amount of care provided, but not based on quality or outcomes. While rising drug prices get more coverage, physician and hospital charges take up a larger piece of the healthcare pie by a wide margin.

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We believe that medicine will become more precise. However, medicine today is generally based on a “one-size-fits-all” practice, and where targeted therapies are possible, it is impractical to scale.

The goal of expanding precision medicine is to provide the right treatment at the right time for every patient. Tailoring treatment starts with a highly-specific diagnosis without unwarranted variation. Based on data integrated from existing sources, adding genomics and radiomics enables a holistic understanding of the individual. These unique characteristics steer the personalization of treatment. A precise understanding of a patient’s condition is the most effective approach to deliver outcomes favorable to all stakeholders.

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Even non-traditional healthcare technology in many forms is pushing its way into the healthcare discussion. Healthtech is 'sexy-wearables' that a track our steps, monitor our heart function, remind us to take our pills and apps tell us when we have appointments. If anything, technology makes a part of our own healthcare accessible and fun, and allows the patient to interface directly with their own health, without using their doctor as a go between, which is especially appealing in the age of WebMD and health-info-by-Google search. Healthtech, including electronic medical records (EMR), should allow for greater transparency, portability, and understanding for all.

But nowhere in these conversations are diagnostics- diagnostic tools that could stratify for response or non-response to drugs and therapies. Diagnostic tests that can assess risk for development of disorders, predict adverse events to be avoided. Diagnostic laboratories and manufacturers are not being called to Capitol Hill to discuss their importance and cost within our healthcare system, to review their latest research and improvements in disease detection and diagnosis. Why? Too boring? More likely, underrepresented and poorly understood. To be clear, part of the problem of the voice of the diagnostics industry is that has never been unified behind a mission in the way that the pharmaceutical or medical industries have been. Instead of uniting an as industry, diagnostics have been infighting over a piece of the pie that seems to be ever shrinking, even as the value of diagnostic technology should be growing in light of technical developments over the past 20 years. Instead, it's been LDT vs IVD. CLIA vs FDA. Small lab vs large lab. Tissue vs liquid biopsy.

Compiled with the fact that diagnostic companies don't have the money to lobby the way the pharmaceutical or medical industries do, and it's no wonder the industry can't find their seat at the table.

Just think about all the areas a more robust diagnostic industry could improve in healthcare. Alzheimer's Disease (AD) is the scariest oncoming health crisis, with 10,000 baby boomers turning 65 every day and 1 in 10 Americans over 65 having some form of dementia. Coupled with the fact that between 2017 and 2025 there is anticipated 14% rise in the prevalence of AD and there are no therapeutic successes to treat this growing population, is the fact that getting a definitive diagnosis of AD before symptoms become debilitating is a challenge. This is compounded by the fact that the recent drug trial failures indicate that, much like cancer, AD is very likely to be subsegmented into multiple molecular and pathological diseases over the coming years, and at therapies will be more effective when targeting those molecular subtypes- in the same way that ALK inhibitors are only given to patients with the EML-4ALK fusion. But, there are no such diagnostics in AD today, and pharma has shown no interest in molecularly segmenting a market that is forecasted to be upwards of $10B annually for the first approved therapeutic. Diagnostic developers are stuck here- since there is no therapy approved, even early diagnosis wouldn't be provide a path for better outcomes, and diagnostics have to prove they change care and improve outcomes in order to get paid. So both diagnostics, and patients it seems, are out of luck.

Similar challenges are present in the diagnosis between asthma and chronic obstructive pulmonary disorder (COPD) and subsequent treatment; in the diagnosis and staging of Non-Alcoholic Steatohepatitis (NASH); in the diagnosis and treatment selection of Multiple Sclerosis (MS); in the diagnosis and treatment of Parkinson's Disease (PD). Diabetes. Too many rare diseases to list. Healthcare as a whole would benefit from better diagnostic tools and more robust participation of the diagnostics industry in our healthcare conversation.

So what can the diagnostics industry do? What are areas that the industry, from large reference labs, to smaller start up labs, to kit and platform manufacturers, can unite behind?

From platform manufacturers to large reference laboratories to CLIA labs with one test, there needs to a stronger voice around the technological capabilities of the industry, the potential for impact on care, outcomes, and cost. There needs to be a way to communicate that solutions to some of the problems our healthcare system is struggling with could be addressed by diagnostic technology- either currently existing, or waiting for investment to be developed. There needs to be a voice on transparency in coverage and reimbursement, which gate market access for all regulated and covered products, since unlike with therapeutics, regulatory approval does not guarantee a single dollar of coverage from any payer, private or government.

A process where stakeholders could identify key areas of need within healthcare that would be improved by investment and development of novel diagnostic tools would spur innovation. Maybe this could unite the diagnostic industry to prove that they are capable of developing novel tools that could dramatically improve patient outcomes, lower overall drug spend, reduce adverse events, reduce hospital stays and readmissions.

Washington DC, are you listening? ■

Hannah Mamuska is Founder and CEO at Alva 10. Alva 10 is focused on moving diagnostics to the forefront of Precision Medicine by executing a comprehensive strategy of value, economics, technology in diagnostic development and commercialization. www.alva10.com

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