Med-Tech Marketing

Analysis, advice and best practices to assist med-tech marketers

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Market Overview
Tectonic Shifts

New devices and diagnostics are being approved, adopted and premium-priced at a furious pace. Now, as a host of new challenges threatens—from economic to promotional to regulatory—are companies equipped to deal with them? **Noah Pines** and **Jana Wolf, PhD,** report

Companies in the device and diagnostic verticals are under pressure like never before. From the largest scanners in imaging suites, to diagnostics that can detect down to a single molecule, even to seemingly mundane hospital wristband printers, these technologies all are a highly valuable—and expensive—part of the healthcare ecosystem, and thus subject to rapidly-evolving changes in that system.

The global medical device and diagnostic market is expected to grow at 4.5% per year (CAGR) between 2012 and 2018, reaching global sales of $455 billion in 2018, according to EvaluateMedTech's consensus forecast of the top 180 global med-tech companies.

That's a quicker pace than the prescription drug market's 3.8% rate during the same time frame, EvaluateMedTech says. But pharma is forecast to catch up, with both industries estimated to grow by about 5% per year from 2015 to 2018.

Economic concerns prompt a focus on engaging the patient

In this technology-driven space, it used to be that deep-pocketed device and diagnostic companies like Johnson & Johnson, Roche, Siemens or Medtronic were driven mainly by innovation, which evolved at a scurrying pace, where a cardiac or orthopedic innovation could become a Smithsonian artifact within 18-24 months after being launched.

But now, companies are facing a much more cost-conscious and thus scrutinizing customer, typically hospitals, who are themselves striving to boost their quality metrics and patient satisfaction.

Firms are looking more at the way their inventions impact customers' ability to survive an increasingly harsh economic reality. "The paradigm is shifting away from incremental design innovation—companies are now asking how they can design products that favorably impact the economics of the hospital," notes Pete Masloski, principal at ZS Associates and leader of its medical products and services practice.

"In the new Accountable Care Organization model, hospitals are going to get a set amount for procedures and won't get reimbursed for re-admission," adds Masloski. "For a device manufacturer, the question is: 'How do I impact those kinds of metrics?' It's a different approach than the fee-for-service world."

Just as in pharma, economic concerns in devices and diagnostics are prompting more of a focus on engaging the patient. "Companies are re-thinking their business model and starting to think about the patient first, not the technology. Engaging customers has been underaddressed, and that is where there is opportunity for disruptive innovation," notes Yannick Sabatian, managing director, Publicis Healthcare Consulting.

Med-tech companies are looking at the "care pathway" and how their inventions not only outpace their competitors, but also foster an enhanced "patient experience" in order to align with the needs of their customers' customers. Two examples are minimally invasive cardiac valves and renal denervation.

Meanwhile, regulatory bodies in the US and EU are becoming increasingly stringent. The level of PMAs in the eight months to August 2013 was down significantly vs. the prior year's first eight months.

This is playing out against the ongoing trend toward the blending of devices and biomedicine to improve outcomes. Such is the case with drug-eluting stents

Top 10 med-tech firms by sales, 2012

Rank	Company	W/W med-tech sales ($ billions)
1	Johnson & Johnson	$27.4
2	Siemens	$17.7
3	Medtronic	$16.6
4	Roche	$11.0
5	General Electric	$9.8
6	Abbott Labs	$9.6
7	Covidien	$9.6
8	Philips	$9.6
9	Stryker	$8.7
10	Essilor International	$5.7

Source: EvaluateMedTech, World Preview 2013

"The paradigm is shifting—firms are asking how they can impact the economics of the hospital."

—Pete Masloski, *principal, ZS Associates*

51% Size of overall med-tech market relative to pharma market by 2018,up from 44.3% in 2005

(Source: EvaluateMedTech, World Preview 2013)

(DES) and orthopedic products like Medtronic's Infuse, which pairs a device with recombinant human bone protein and is designed to both stimulate bone formation and provide a growth scaffold.

As the age wave starts crashing across the beach, demographics are causing changes in the diagnostics business. The needs of the baby boomer generation coupled with favorable reimbursement have driven hospitals and stand-alone diagnostic centers into a heated competition.

However, the economic downturn since 2007 has dramatically dampened large capital expenditures, which has negatively impacted makers of imaging equipment. This has led them to start looking overseas toward the emerging markets where there are both similar and different needs but also smaller wallets.

"With the economic downturn, there was a pivot to start developing products tailored for these markets, even building R&D centers there to better appreciate their unique needs," points out Masloski. "Every company is seeking the next medical breakthrough, but what has become more important is how you can impact economic value."

The in-vitro diagnostics business—the largest segment within med-tech and one of the fastest growing, according to EvaluateMedTech—is supporting the burgeoning shift toward personalized medicine, which is nowhere more apparent than in the treatment of cancer, as well as supporting the pharmaceutical industry's appetite for illuminating targets for new drug discovery.

Some of the larger medical products firms, like Abbott and Covidien, have split their med-tech from their pharma units, becoming nimbler players in this area. And smaller biotech companies are developing personal diagnostics which, in some cases, are getting picked up by Big Pharma.

As the cost of medication non-adherence grows (to $290 billion at last count), device makers see opportunity in cracking the compliance code, as well.

There is also an emerging array of personal diagnostic devices, which can include glucose monitors, even to the latest FitBit, all of which are subject to consumer rules and the "Wal-Martization" of healthcare.

Ned Russell, managing director of Publicis shop Saatchi & Saatchi Wellness, points out, "So if you are in the glucose-monitoring business, you might come up with a better mousetrap, but then you have payers willing to pay less, and Wal-Mart introducing their own devices [on the cheap]. The patient then has to make a decision as to whether or not they will manage their condition by almost the way they lead their life."

Adds Russell, that decision comes down to: "Do they cheapen out or...do they value the device such that they will have to pay more to get the better product? At the end of the day, in corporate-strategy speak, every large pharma and device company talks about 'patient platform,' and they spend a lot of money learning about how patients approach their disease states." ■

Top 10 med-tech segments by sales, 2012

Rank	Segment	W/W sales ($ billions)
1	In vitro diagnostics	$43.6
2	Cardiology	$38.1
3	Diagnostic Imaging	$36.1
4	Orthopedics	$32.7
5	Ophthalmics	$23.6
6	Endoscopy	$17.7
7	Drug delivery	$17.7
8	General & plastic surgery	$13.4
9	Dental	$12.6
10	Wound management	$11.9

Source: EvaluateMedTech, World Preview 2013

"You might come up with a better mousetrap, but payers may be willing to pay less. Patients have to decide how to manage their condition."

—Ned Russell, *managing director, Saatchi & Saatchi Wellness*

14 The number of new PMAs the FDA approved in 2013 (to Aug. 31), down 42% vs. same point in 2012

(Source: EvaluateMedTech, World Preview 2013)

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Unique Challenges
A Perilous Pace

Its light-speed development times and regulatory cycles, along with distinctive sales structure, set the device and diagnostic industry apart from its biopharma counterpart. The downside: firms can lose market share much more quickly

In certain ways, diagnostics and devices are similar to pharmaceuticals, yet there are a number of challenges that make med-tech sales and marketing unique.

Sales structure in this market is slightly different from its biopharmaceutical counterpart. Healthcare professionals are still important, but hospital administrators, group purchasing organizations (GPOs) and distributors also play a pivotal role.

"The challenge that you have is that you don't have a direct field force [like you have] in pharmaceuticals and biotech," says Mark Mahmood, VP of marketing at Obalon Therapeutics. "In devices you work through distributors who are carrying a portfolio of products. How, then, do you incentivize and communicate via those representatives so that they carry your message?"

Still, "Barriers to entry are lower than in the pharma industry," adds Mahmood. "You can be the market leader for 6-9 months, and you can lose your market share quickly. The innovation and product lifecycle in medical devices is light-speed as compared to pharma."

"There are a number of challenges exclusive to devices and diagnostics

On the other hand, sales cycles can take longer and sales-tracking is oftentimes harder to do, as sales are not necessarily as visible as is, say, pharmacy level data for prescription drugs. The sales process and the necessary long-term relationships are more similar to sales in IT than they are to the typical pharma sales rep's product detail.

"Fundamentally, it means understanding the customers' buying process…you need to understand what is important to the various stakeholders and how they interact," states Jim Adelizzi, principal at ZS Associates. For example, he adds, "In oncology, the pathologist is becoming more important…for the adoption of the diagnostic, and you need to understand how the buying process works, what the turnaround times are that work for physicians, and how they want the information presented."

Although gear makers are still grappling with the uncertainties of healthcare reform, there's little doubt that escalating macroeconomic pressure will prompt them to evolve business models to deliver better outcomes and lower costs. In this sense, med-tech is dealing with the same issue as pharma.

From large hospital systems demanding more value for their buck, to individual baby boomers willing to pay out of pocket for improved quality of life, the imperative to improve the value proposition is forcing companies to re-think their core business model. The most important question is whether the premium-pricing model will remain intact.

Some of the most dynamic sectors are cardiovascular and orthopedics, as they are large and thus receive high levels of funding. That can make them a target for cuts.

"One of the challenges facing those sectors is that they come up high on the radar of hospital executives and purchasing; both markets have been under a lot of pressure from changes in industry. You have large

Device tax hits home, costs jobs

Republicans, vocal in their opposition to the 2.3% medical device tax that went into effect in 2013 to help pay for the Affordable Care Act, haven't been able to repeal it. But their October attempt threatened to do just that.

During the government shutdown, repealing the tax was one of Senate Minority Leader Mitch McConnell's (pictured) conditions for ending a standoff. The Kentucky republican's efforts were stoked by the med-tech industry's anti-tax lobbying campaign, which claims the levy would do significant harm.

In a joint announcement, the Medical Imaging & Technology Alliance (MITA), the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA) said that medical device manufacturers had paid an estimated $1 billion to the IRS for the tax after the first six months of 2013.

AdvaMed added that the tax could ultimately cost more than 45,000 jobs. Meanwhile, med-tech giants like Boston Scientific, St. Jude Medical and Quest Diagnostics were among those announcing job cuts in 2013.

The eventual deal to reopen the government and avoid a debt crisis failed to kill the tax, but talk of a repeal, or at least a delay, may surface again if the government faces another shutdown at the start of 2014.

"You can be the market leader for 6-9 months, and then lose your market share much more quickly"

—Mark Mahmood, *VP of marketing, Obalon Therapeutics*

$30B

The amount the 2.3% medical device tax is expected to raise over the next decade to help cover the cost of Obamacare

Unique Challenges
A Perilous Pace

companies experimenting with innovation…with deep pockets," says Masloski.

Premium pricing has been a fundamental assumption driving med-tech innovation. However, as the Affordable Care Act and general macroeconomic factors transfer risk to providers, such as the new Accountable Care Organization (ACO) model, the threshold of evidence required to secure reimbursement will be driven higher.

"Comparative effectiveness is going to get bigger," predicts Rhonda Greenapple, chief strategic officer and founder of Reimbursement Intelligence. "Hospitals and providers are going to start benchmarking, but right now, they don't do a lot of that. They will eventually start to really aggregate data, and then analyze the data."

Not only that, but with consumers assuming greater out-of-pocket costs, the question of price will become increasingly important.

"Every company is trying to get at the next major clinical breakthrough," points out says Pete Masloski, Principal at ZS Associates and leader of its medical products and services practice. "But what has become more important is impact on economic value."

In response, innovator companies are focusing on

"Med-tech is revamping sales teams to better align with IDNs

the global opportunity and trying to broaden their offering. While the US and Western Europe are the largest diagnostic and device markets, Singapore, Hong Kong, Taiwan, South Korea, Germany and Canada are also important growth regions. China, India and Brazil are currently viewed to be the most important emerging markets for med-tech.

Many companies are also facing more of a sophisticated enterprise-level vs. individual physician purchasing decision. These decision-makers have a wider host of considerations than just clinical criteria—they also have to consider value, compatibility, implementation cost and a host of other organizational factors.

"There is a ridiculous amount of pressure that hospitals and providers are facing, with a lot of uncertainties of what will hit them in two to three years," asserts John Park, VP of marketing and R&D at PDC Healthcare, a maker of patient ID wristbands and labeling products used in healthcare settings. "From a reimbursement standpoint, they don't know what the net effect will be, aside from [knowing they] have to have a better cost position."

"Before, our business was all about selling customers more value in a new piece of equipment that was built to satisfy physicians' preferences," observes ZS's Masloski. "Now a lot more is being shifted into non-physician preference items—hospitals and providers are mainly looking at whether new equipment will improve patient care, patient safety and/or patient satisfaction. If it is not going to do that, they are reticent to take on additional costs. The days of 'paper value,' or theoretical value, are over. Hospitals and providers are going to start measuring whether or not what you say is what it can do."

In response, med-tech companies are "…increasing their investments in key account management, particularly geared toward larger Integrated Delivery Networks (IDNs) that are becoming more important in the decision making process," adds Masloski. "Investments have been both in terms of increasing the sizes of those teams as well as restructuring sales forces to better align with serving IDNs."

At the same time, companies are looking at private-pay options. Obalon's Mahmood explains the advantages and pitfalls of a cash-paying customer this way: "When the patient pays cash, they are more engaged—more fully committed to the therapy—which drives an opportunity for a very strong outcome. At the same time, they are very demanding on your product. They have paid their own money and they expect a positive outcome. It is therefore critical to educate the physician to set expectations around product performance, as well as touch-points with the patient, especially in addressing metabolic diseases such as obesity."

Besides the big picture macro-headwinds, companies are facing unique organizational challenges as they increasingly offer personalized medicine, bundle therapeutics and companion diagnostics, thus driving treatment decisions through biomarker detection (see Chapter 3).

In the US, the medical device tax and healthcare reform are creating further challenges. Whereas in the emerging markets, medical device policies are just evolving, the US medical device excise tax of 2.3%, on such items as defibrillators and pacemakers sold in the US (but not on those exported), went into effect in 2013 as a way to help cover the cost of Obamacare. It's expected to raise $30 billion over the next decade. ■

"They don't know what the net effect will be, aside from knowing they need a better cost position."

—John Park, *VP of marketing and R&D, PDC Healthcare*

3.9%

CAGR for R&D spend in global med-tech sector, 2012-18

(Source: EvaluateMedTech, World Preview 2013)


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New Frontiers
The Dx-Rx Nexus

Of all the nascent med-tech on experts' radar screens, the one they mention most often is companion diagnostics, for its potential to help companies become more personalized and patient-centric

Companion diagnostics—already fueling a revolution in conditions such as cancer, HIV and cystic fibrosis—is likely to expand as it makes treatment and new drug development in other complex illnesses ultimately more efficient.

"Companion diagnostics will help to fulfill the promise of personalized medicine," asserts Chris Tobias, PhD, EVP, chief scientific officer at advertising agency Dudnyk. "In the next five to 10 years, I expect that all new therapies in difficult diseases like oncology will have a companion diagnostic to determine whether or not the person is a candidate for the medication, or if the person will metabolize the drug faster or slower."

Driving the adoption of companion diagnostics is that both cost and turnaround time has plummeted, making them a more efficient part of everyday medical practice. "These tests used to take so long, and were so expensive, that they were impossible," says Stephen Kondor, VP of Quintiles Commercial Solutions. "Now there is opportunity for a better, more comprehensive intervention for the physician."

"Companion diagnostics may fulfill the promise of personalized medicine

Existing examples include such drug-device pairings as Pfizer's Xalkori (crizotinib), approved in 2011 for treating some patients with late-non-small cell lung cancer with a genetic mutation that can spur the growth of cancerous cells, along with Abbott Molecular Diagnostics' test for the mutated gene, called the ALK FISH test. Another example: Genentech's melanoma drug Zelboraf (vemurafenib), also approved in 2011 with a test from Roche Diagnostics to screen for the BRAF V600 mutation.

For pharma, marketing these pairings takes some getting used to. "Historically, the therapeutics companies are good at marketing therapeutics—yet increasingly, the diagnostic is the gatekeeper to tapping the potential. And commercializing a therapeutic associated with a diagnostic requires an in-depth understanding of the stakeholders and the diagnostic 'buying process,' which are often very unique and are very complex," explains Jim Adelizzi, partner at ZS Associates. To avoid failure, he encourages companies to view the diagnostic as its own product, yet link them together (see sidebar).

Take oncology. Most companies think primarily about the oncologist being the quarterback. Yet, according to Adelizzi, with companion diagnostics driving treatment decisions, the role of the pathologist is becoming more important. "If you adopt the philosophy that the diagnostic is its own separate product, and you are coordinating the launch approach, you have someone on the team that fundamentally owns that work-stream, and that is well-coordinated with the therapeutic."

Adelizzi credits Genentech, GlaxoSmithKline and Pfizer as trailblazers of effectively coordinating their therapeutic and diagnostic marketplace activities.

New pairings test pharma marketers

Pfizer, thrust into personalized medicine with the 2011 approval of Xalkori (crizotinib), highlights the challenges pharma faces as diagnostic-device pairings become more common.

Xalkori is for some patients with non-small cell lung cancer who have a genetic mutation that can fuel the growth of cancerous cells. The FDA simultaneously approved a test from Abbott Molecular Diagnostics for the mutated gene, called ALK (anaplastic lymphoma kinase).

At the New York Biotechnology Association in May 2012, Nancy Steele (pictured), Pfizer VP of strategy, said selling the product pairing was requiring the company to think differently.

"Candidly, we ask ourselves every day, 'Are we investing enough in the ALK test?'" she said at the time.

"It's so deep in our DNA that of course we're going to put [out] a field force; they're going to have detail aids," Steele added. "[But] how do you really turn peoples' heads around to the idea that if you're not spending 80% of your dollars on getting that test done and finding those patients that need that drug, there's something wrong?"

During the first nine months of 2013, Pfizer said it sold $193 million worth of Xalkori, more than double the med's global sales during the first nine months of 2012—evidence that its efforts to identify appropriate patients are gaining steam.

"In the next five to 10 years, all new therapies in difficult diseases will have a companion diagnostic"

—Chris Tobias, *PhD, EVP, chief scientific officer, Dudnyk*

$64.7B

2017 sales forecast for the in-vitro diagnostics market, up from $45.7B in 2012

(Source: Frost & Sullivan, 2013)

Marketing personalized medicine also changes the sales-force dynamic, particularly in terms of the sophistication level of the conversation reps have with clinicians. "Those commercial organizations who can speak not only the language of treatment, but also the language of diagnosis, are very well positioned to talk credibly to physicians," Adelizzi asserts.

"If you are in the personalized space," he adds, "your reps have to master the whole continuum—it is a much more rigorous sales training, and parallel to what happens in physician training. It is going to be a much more sophisticated, science-based conversation."

Test makers in this therapeutic area are driving toward ever more precise results. "In cancer screening, you need the most sensitive tests so that you can catch it early enough and have a treatment regimen on-board as soon as possible," asserts Paul Chapman, CEO of life sciences firm Quanterix, which is developing ultrasensitive diagnostic technology the firm says can measure individual proteins at concentrations 1000 times lower than the best immunoassays available.

As more therapeutics go the personalized route, it will make medical decisions more complex. Diagnostic tests can be helpful across the entire spectrum. "Companion diagnostics are used not only in development, but will also help determine which drug candidates you can get [approved] faster, and which are not going to make it," explains Quintiles's Kondor.

"Marketers must be able to speak the language of therapy and diagnosis

"They are becoming more important as part of clinical trials—in oncology for example—and are very important for regulatory bodies," he says. "Not only that, but then you need the test on the back end, to demonstrate the health economic outcomes of these drugs to payers."

Quintiles recently announced that it will partner with US Oncology Research and McKesson Specialty Health to investigate how "pre-profiling" cancer patients may support physician treatment decisions, including the identification of appropriate clinical trials for patients.

While diagnostics companies are helping medicine become more personalized, device company pipelines are brewing with new technology aimed at solving the adherence conundrum plaguing chronic diseases, such as those in the metabolic space.

"Many of the chronic diseases affecting us—diabetes, glaucoma, obesity, for example—are challenging to treat because people don't take their medicine as well as they should," says Nancy Beesley, co-founder and chief marketing officer of ad agency HCB Health.

Beesley says she sees her device clients striving to solve this by creating more smart, implantable devices that remove the human element. One area poised for growth in the next decade: drug-eluding products. For example, she offers, "A stent placed in your eye could provide a perfectly titrated dose of glaucoma medicine, thus keeping [the disease] under management."

With Baby Boomers seeking to outlive their parents, Beesley envisions a cornucopia of new devices: new intraocular lenses improving sight, joint-replacement technology that incorporates robotics, new spinal technologies, even devices that address the obesity crisis. Others may re-task existing technology to focus on prevention, especially in the hugely expensive categories of cardiology and metabolic disorders.

The agency exec also sees a trend toward device manufacturers—especially those whose products are aimed at "lifestyle" indications—trying to market toward patients able to pay out-of-pocket. At the same time, Beesley encourages manufacturers whose products will reduce the need for "heads in hospital beds" to try to secure insurance coverage.

"Any time there is a device that will prevent office visits, like one that stabilizes blood sugar and thus potentially avoids hypoglycemia," she says, "those are the kinds of technologies that will thrive under ObamaCare." ■

"In cancer screening, you need the most sensitive texts so that you can catch it early and have a treatment regimen on-board."

—Paul Chapman, *CEO, Quanterix*

Regulatory Environment
The Plot Thickens

Getting a device approved as a 510(k) predicate filing is easier than securing the FDA's nod for an NDA. But the PMA process is quite rigorous, raising important considerations for companies

Changes in the regulatory environment are making the process more stringent for medical device and diagnostic manufacturers. These shifts have coincided with the increasing complexity in the nature of products themselves.

Since Congress passed the Medical Device Amendments (MDA) to the Food, Drug and Cosmetics Act (FDCA) in 1976, it has been the job of the Center for Devices and Radiological Health (CDRH) and the FDA to ensure safety and efficacy of devices and diagnostics (its parallels on the drugs side are CDER and CBER). And just as the pharma industry pays user fees to the agency in exchange for an assurance of a timely review (a PDUFA date), med-tech pays application fees and gets a MEDUFA date (both were renewed in 2012).

"There has been a lot of pressure from the med-tech industry on the [FDA review] process," says Wayne Pines, a former FDA associate commissioner, "much more so than the drug area because there is more experience with user fees for Rx drugs than for medical devices."

In devices, says Pines, "the products tend to be more diverse and more complex [than drugs]. Industry wants to make sure that FDA has the expertise to do the reviews properly." And to a certain extent, it's succeeded.

Two procedures are possible for premarket review procedures: The "premarket approval" (PMA) and the "pre-market notification," also referred to as the 510(k). While the PMA is equivalent to the new drug application (NDA) in that the manufacturer has to prove safety and efficacy in the form of clinical trial data, the 510(k) only requires the manufacturer to demonstrate that the device in question is substantially equivalent to an already approved 510(k) device.

Depending on the potential harm a new device can actually cause, it is classified as Class I, Class II or Class III. Class I devices are of such low risk that they are usually exempt from any premarket review (e.g., tongue depressors, elastic bandages, reading glasses).

Class II devices are potentially of moderate harm to the patient and usually undergo a 510(k) procedure (e.g., electrocardiographs, powered bone drills, mercury thermometers), while Class III devices are of such high risk or so novel in their application that they need to go through a full PMA (e.g., pacemakers and replacement heart valves).

Most med-tech products that reach market have gone through the 510(k) process. But regulatory standards are tightening.

Of the 50,000 devices that entered the market between 2003 and 2007, according to a 2009 report by the Government Accountability Office (GAO), 71% were Class I, 26% Class II, and 2% Class III; 29% of Class III devices were allowed to enter the market with merely a 510(k) process, which is why the GAO

"The FDA doesn't get as 'in the weeds' with what we are saying promotionally"

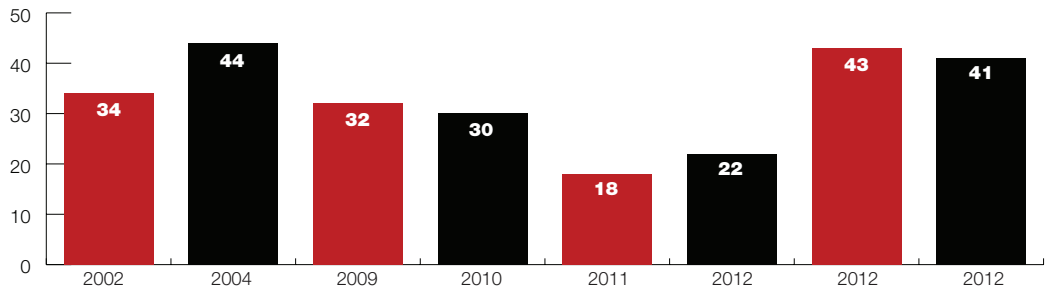
—Nancy Beesley, *CMO, principal, HCB Health*

90 The number of days it takes for the FDA to review most 510(k) applications

(Source: GAO, 2009)

Keeping count

FDA's approval count for devices*. For the eight months to Aug. 2013, its new PMA total (14) was down 42% vs. the same period in 2012.



*Includes for first-time PMAs, HDEs and PDPs
Source: EvaluateMedTech, World Preview 2013

Regulatory Environment
The Plot Thickens

requested that they be handled more stringently, and the HHS agreed to this.

Thus, more stringent regulatory reviews are underway, affecting all parties both financially as well as regarding the timing of the reviews: The aforementioned GAO report states that a 510(k) submission costs the FDA about $18,200 to review, while filing fees are $3,693; 90% of these submissions are reviewed within 90 days.

PMA submissions, on the other hand, cost the FDA about $870,000 to review. The standard filing fee is $200,725 for a PMA submission and the goal is to review 60% of these submissions within 180 days and 90% by day 295. The review process a diagnostic or device falls into thus has an obvious financial and time impact and might be a make-or-break factor for the product in question.

As of August 2013 (the latest data available at press time), the FDA had only approved 14 new PMAs, a 42% decline compared to the same point the previous year.

One area where the CDRH may be taking more time is when a diagnostic is used to determine if a patient will react well to a drug—a so-called companion diagnostic. In such cases, the center coordinates with CDER or CBER.

"The review process is a make-or-break factor for the product in question

"The industry would say that when the centers have to work together, there are inevitable delays because the centers do not coordinate as efficiently as the industry would like," adds Pines. "The agency is conscious of that and it is an issue they are trying to address."

From a marketing perspective, the tightening regulation makes the use of certain media channels, particularly on social networks, increasingly difficult. "It is the toughest for a device company to get into all of the social [media] stuff, because of the regulations," says Ned Russell, managing director, Saatchi & Saatchi Wellness. "If you invite people and they report an adverse event, you have to report it."

Then again, observes Nancy Beesley, chief marketing officer and principal at ad agency HCB Health, with devices and diagnostics, "The FDA doesn't get as in the weeds with what we are saying promotionally."

There have been exceptions. Recently the agency sent a Warning Letter to Google-backed genetics firm 23andMe saying it must discontinue marketing of its Personal Genome Service (PGS). PGS, according to the firm's website, uses customers' DNA to provide "specific health recommendations" and help them "learn about and explore their DNA."

The company ended up halting all TV, radio and online advertisements for the service a mere three months after initiating the DTC campaign. FDA concerns centered on the device's growing list of medical uses appearing on the company website. Some of those uses, FDA said, have "not been classified and thus require premarket approval."

In the letter, regulators said some of those intended uses, like "assessment for BRCA-related genetic risk and drug responses," were "particularly concerning," due to the chance of false-negatives and false-positives, which could lead to unnecessary treatment or a missed diagnosis.

In Europe, medical devices need to be approved according to the Medical Device Directive, which is intended to harmonize approvals across Europe. Successful products then receive a CE mark. The directive was updated in 2007 and compliance became mandatory in 2010.

Other than in the US, the CE marking is a self-regulation. For low risk products, manufacturers are allowed to self-certify.

The European Commission has published a new legislation in the form of two draft regulations to govern the regulation of medical devices and in-vitro diagnostic medical devices in Europe. The Regulations will replace the directives which currently provide a regulatory framework and are expected to come into effect in 2014.

It also likely means that, like their US counterparts, European regulatory authorities are ratcheting up scrutiny for devices and diagnostics. Going forward, manufacturers active in the European market will face a higher regulatory bar. ■

"There has been a lot of pressure from med-tech on the FDA review process"

—Wayne Pines, *former FDA assoc. commissioner*

29%

Amount of Class III products able to enter market via 510(k) approval 2003-07

(Source: GAO, 2009)

Standout Marketing
Healthy Forays

In the medical device and diagnostic sector, consumer advertising and marketing is still newly forming muscle. Early efforts have seen success by forging emotional bonds

DTC advertising is still a relatively new phenomenon in device and diagnostic marketing. Those companies that have found success have leveraged a deep understanding of consumer emotional insights to motivate dialogue between physician and patient. This is especially true in categories where the individual plays a larger role in the treatment decision.

"The device is with the patient 24/7; it's an extension of themselves," explains Nancy Beesley, chief marketing officer and principal, HCB Health. "Any time a patient is part of the decision-making process, it's critical for device makers to get into the psyche of the patient, to get inside the emotional connection the patient has with that device."

Choosing an artificial knee is a good example, given the big patient component to the decision-making process. Stryker had marketed its ceramic Triathlon Knee to patients and surgeons based upon a "single-radius design philosophy" messaging approach, but that didn't resonate.

GSW, part of inVentiv Health, re-branded the product the GetAroundKnee and took a more right-brained approach to highlighting the advantage of a circular vs. oval knee (see picture). It targeted Baby Boomers through a series of clever, catchy ads: a nostalgic bike-riding scene, an SUV and bowling. These themes appeared in :30 TV spots, as well as in print and online. (The new messaging was introduced first to the sales force and then to surgeons.)

The essence of the campaign was the agency's ability to bring the knee's circular design to life in a simple manner, spurring knee-replacement candidates into dialogue with their surgeons. During year one of the campaign, surgeon locator look-ups reached 100,000, calls to surgeons 9,000 and unique visits to the brand microsite 500,000.

In 2013, Stryker launched a :60 spot while expanding into such media as outdoor, theaters and PCP seminars, all leveraging the core design philosophy and message. Stryker started to roll out a professional campaign internationally, too.

Med-tech companies are also finding success by engaging patients where they congregate online, particularly on social networks like Facebook and YouTube. "Patients are getting more involved in decisions affecting devices and diagnostics, and for some businesses this means social media is a more natural [choice]," notes Pete Masloski, a principal at ZS Associates and the leader of its medical products and services practice.

"Leverage emotional insights to spur the right dialogue

He points to Medtronic Diabetes, whose home-grown Facebook community reached 100,000 fans in November 2012, a mere seven months after launch and with a relatively limited investment of about $400,000. It's aimed at supporting the firm's diabetes customers, building loyalty and driving awareness of its core insulin pump therapy and continuous glucose monitoring products.

According to Medtronic, the community became the number-one diabetes brand on Facebook (as of early 2013). Efforts like a "Share Your Story" app, as well as coupons and giveaways, daily posts, and contests like one soliciting back-to-school tips have spurred customer engagement. Medtronic promotes the community through newsletters, supply boxes, the field sales force and its customer service organization.

Another way med-tech firms are easing into patient marketing—and seeking to bridge doctor and patient silos—is through mobile, particularly disease-specific

"It's critical for device makers to get into the psyche of the patient"

—Nancy Beesley, *principal, HCB Health*

100K

Number of surgeon locator look-ups during year one of Stryker artificial knee campaign

apps that encourage patients to keep an ongoing journal or diary of their chronic disease experience. For instance, Stryker debuted a free pedometer app as part of its GetAroundKnee promotions.

"These apps allow people with chronic illnesses to take charge of their own health by becoming more accountable," explains Beesley. "Armed with a chronicle of what happened between doctor visits, [they] allow a more productive conversation to happen between the patient and the doctor."

Apps that display data visually also help doctors spot trends and track factors that affect disease management, she says. And for patients who regularly log their activity and how they feel, it creates more accountability. "That is what keeps patients healthy. It is making medicine smarter and more efficient."

Another standout example is molecular testing firm Crescendo Bioscience's Track My RA, a customizable app which allows people living with rheumatoid arthritis to report on the location and intensity of their RA pain, morning stiffness, as well as their general functionality, fatigue level and other symptoms. Intuitive data visualization allows them to self-monitor and share experiences with their physicians. ■