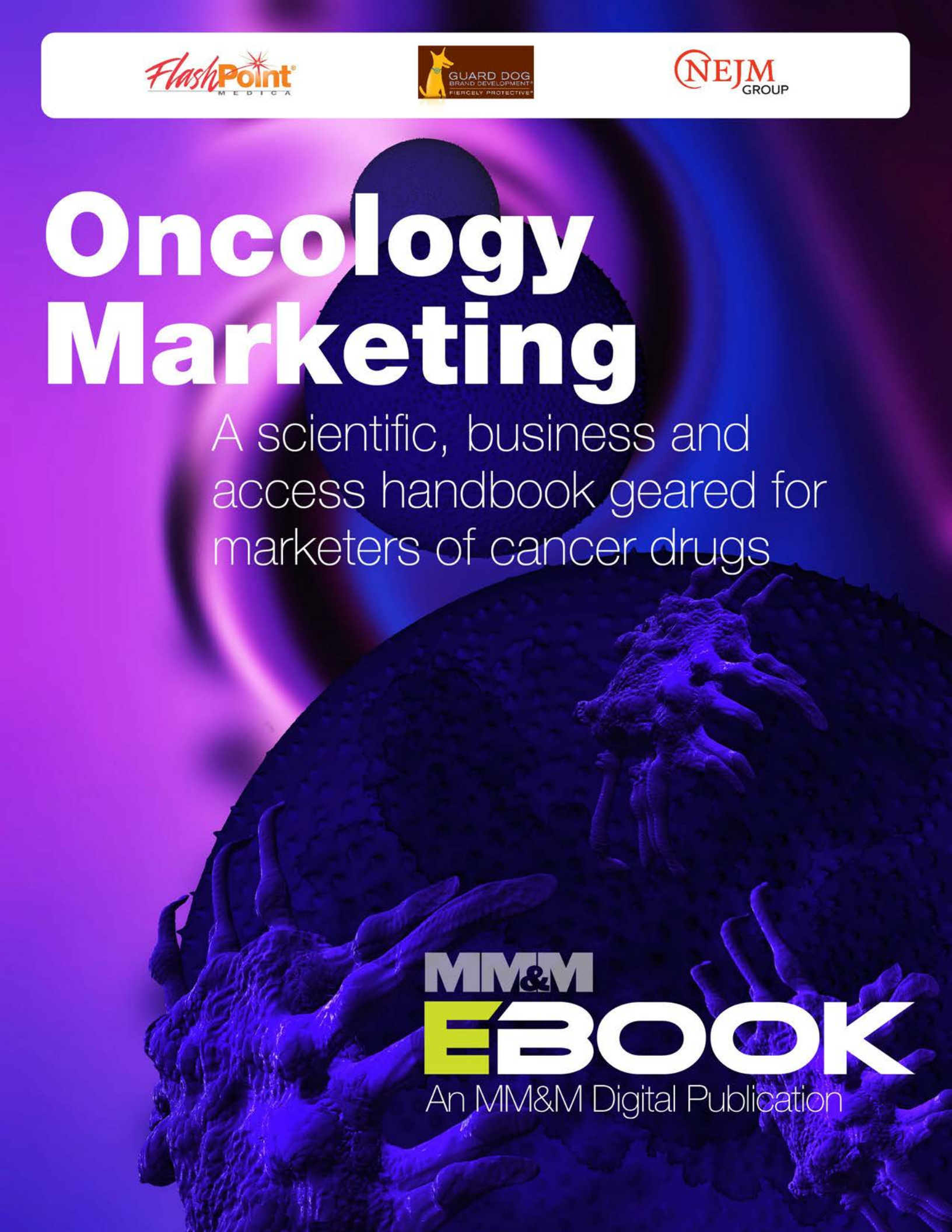
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Market Overview
A Formidable Foe

Treating cancer remains elusive. At the same time, exciting progress on the genetic level is shifting the goals of cancer care. **Noah Pines** sums up the significant scientific, business and access trends in the oncology field

Marking the 43nd anniversary of the US government's declared "war on cancer," the American Cancer Society's latest annual report, released in January 2014, offered some good news: Between 1991 and 2010, there was a 20% decline in the overall cancer death rate.

At the same time, researchers for the World Health Organization's International Agency for Research on Cancer said they expect that, globally, the annual number of new cancer cases will jump from 14 million in 2012, to 22 million over the next 20 years—a grim reminder that cancer is still a major mortality threat.

According to experts, treating cancer remains so elusive because it's not one single disease with a single cause, but rather a collusion of proliferating cells that betray the host, causing genetic mutations and biological actions that create tumors.

Tumors can grow and evolve differently in each individual. Scientists have identified some of the genetic factors that cause tumors to start and spread, and targeting these mechanisms with "smart," personalized medications has been the most exciting area of new development progress.

An example was the July 2013 approval of Boehringer Ingelheim's Gilotrif (afatinib) for people with non-small cell lung cancer (NSCLC) whose tumors express specific types of gene mutations, as detected by a Qiagen diagnostic test. It was one of eight new cancer drugs, half of them first-in-class, sanctioned in 2013 by the FDA, out of a total of 27 novel new medicines.

"Science is revealing the complexity of cancer and the significant heterogeneity across patients who develop the disease. This better understanding is yielding progress in every modality: diagnostics, surgery, radiation, and drug treatments," said Ganesh Vedarajan, managing principal on ZS Associates' executive team and leader of the firm's global medical products and services practice.

2013 brought even more momentum on the targeted-therapy front, including the February approval of Genentech's Kadcyla (T-DM1 or ado-trastuzumab emtansine), the first antibody-drug conjugate sanctioned by FDA for treating HER2-positive metastatic breast cancer.

Along with other cancer drugs, therapies paired with companion tests that can detect a mutation—so-called targeted treatments—lifted the overall oncology market by 7.3% in 2012 to $25.6 billion, according to figures from IMS Health.

However, as cancer treatment becomes increasingly personalized, one problem is becoming frustratingly common: cancer cells can often build up resistance.

A family of agents in the pipeline, the PD1/PDL1 immunotherapies, possibly offer a more durable effect and sustained response (some say long-term survival)

"Science is revealing the complexity of cancer... across patients who develop the disease."

—Ganesh Vedarajan, *managing principal,ZS Associates*

22M The number of annual cancer cases projected globally by 2032

Source: International Agency for Research on Cancer

Top 10 oncology agents, 2012

Category leaders, ranked by 2012 US sales

Rank	Product	Manufacturer	US sales
1	Rituxan	Genentech/Roche	$3.2B
2	Avastin	Genentech/Roche	$2.7B
3	Herceptin	Genentech/Roche	$1.9B
4	Gleevec	Novartis	$1.8B
5	Alimta	Eli Lilly	$1.2B
6	Eloxatin	Sanofi	$1.1B
7	Xeloda	Genentech/Roche	$724.3M
8	Velcade	Takeda	$714.6M
9	Erbitux	BMS/Imclone	$690.4M
10	Xgeva	Amgen	$663.4M

Source: IMS Health

Market Overview
A Formidable Foe

by retraining the body's immune system to kill cancer cells.

These antibodies, shown to work across multiple tumor types, have multi-billion-dollar potential. In a November research note, Leerink analysts predicted that, over the next decade, the market for immuno-oncology drugs could reach $29 billion, "with realistic upside to $34 billion."

Analysts are closely watching a PD-1 race brewing among companies including Bristol-Myers Squibb, Merck and Roche, and 2013 was a breakout year for data and investment in so-called checkpoint inhibition.

On the business front, the big trend has been increased provider-side consolidation and other changes in the business model. With cancer care migrating from the community-based setting to large centers, due to burgeoning administrative requirements, community oncology practices are finding it harder to survive independently.

These large cancer systems are growing, boosting their ability to influence the behaviors of network physicians by institutionalizing treatment protocols and pathways. Said Vedarajan, "The consolidation will result in fewer and more-integrated care settings. There will be more institutional policies and oversight of care."

"A better understanding of cancer is yielding progress in every modality

From a payer standpoint, insurers are starting to scrutinize cancer treatments more actively due to the skyrocketing, double-digit spending growth in specialty medicines. According to ZS Associates, MCOs' usage of prior authorizations is on the increase in response to growing competition in several tumor types.

While in years past, manufacturers could expect virtually unlimited access to new cancer drugs, they are now having to set up the value of their products as part of laying the foundation for a new medication launch.

"Companies need to see payers as at least as important a customer as physicians; and increasingly need to make a case, through outcomes and pharmacoeconomic data, that spending X amount on a therapy for Y months of survival benefit is compelling," said *in*Thought analyst Dr. Marc Engelsgjerd.

And despite a fecund pipeline, manufacturers are facing more of an uphill battle in bringing educational product messages to oncologists. According to ZS Associates' AccessMonitor, oncologists are the most restrictive specialty, with nearly two-thirds placing moderate-to-severe restrictions on sales rep visits.

This represents an important challenge for manufacturers as they bring new medicines to market and need the time to educate physicians.

"The biggest challenge is that most oncologists are seeing tons of patients with different types of cancers and are faced with an increasing number of drugs on the market that they need to be aware of and understand," said Ariella Evenzahav, PhD, a former Pfizer marketing research director turned industry consultant.

"They really don't have much time to engage with sales reps or to read company websites to get information," said Evenzahav. "Rather, they are seeking much more specific information, such as, 'Is there an adverse-event management protocol in place for drug X?' or 'How do I get this drug to be covered for my patient?' Add to this the increasingly tight PhRMA rules about engaging oncologists, and the going gets tougher." ■

"They really don't have much time to engage with sales reps or to read company websites."

—Ariella Evenzahav, *PhD, marketing research consultant*

$74-84B

Projected sales in oncology therapy area in 2017

Source: IMS Institute for Healthcare Informatics

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Source: *The Essential Journal Study, The Matalia Group, 2013*

The R&D Environment
Advancing Antibodies

A set of treatments that harness the body's own immune system to recognize and attack cancer cells has the oncology community abuzz. Analysts say this class of drugs is a commercial near-certainty of large proportion.

The most significant oncology new drug story, and potentially the most exciting new class in the entirety of the pharma pipeline—not just in this therapeutic category—is the PD-1/PD-L1 (programmed death receptor-1) cancer immunotherapy candidates.

This pathway, which is common to solid tumor conditions such as melanoma, non-small cell lung cancer (NSCLC) and bladder cancer, is the focal point of an intensively competitive race among Bristol-Myers Squibb and Merck, as well as Genentech and, more recently, AstraZeneca.

"PD-1/PDL-1 has everyone excited and refocused on the potential of essentially assisting the patient's own immune system to fight off a tumor," states *in*Thought analyst Dr. Mark Engelsgjerd.

Were any of these contenders to reach market, they would continue drugmakers' recent hot streak of first-in-class approvals. Last year—out of the eight new cancer drugs green-lighted by the FDA—four represented a unique mechanism of action.

There's also a good chance they could pass muster with the agency sooner rather than later. Historical data show that cancer drugs had the highest rate of first-cycle approval, while GI was a close second. Pulmonology, cardiology, and dermatology were at the bottom (see table).

"The remarkable characteristic of these specific treatments is their ability to harness the body's own immune system to recognize and attack cancer cells. Unlike targeted agents, which are often directed to single genetic aberrations and quickly become ineffective as tumor cells mutate and develop resistance, immunotherapies like the anti-PD-1/ anti-PDL-1 class can provide a much longer duration of response (DOR)," adds ZS principal Sharon Karlsberg.

There have been consistent responses demonstrated in early clinical data against a host of different tumor types to the point where this approach should be considered "de-risked," according to Bernstein Research analyst Dr. Tim Anderson, in a recent research note, making this class of drugs "a commercial near-certainty of large proportion."

Other analysts have forecast a roughly $30-billion market for immuno-oncology drugs over the next decade.

Three new agents are leading the way, with exciting new Phase-I data in metastatic melanoma (mM) presented for all three drugs at the American Society for Clinical Oncology (ASCO) meeting in 2013. The two furthest along in clinical development are Bristol-Myers Squibb's nivolumab, an anti-PD-1 therapy and Merck's MK-3475, which in Jan '14 filed a rolling BLA

"Everyone is excited and refocused on the potential of essentially assisting the patient's own immune system."

— Dr. Mark Engelsgjerd, *analyst,* in*Thought*

$29B

The projected market for immuno-oncology drugs by 2023

Source: Leerink

First-time success

Cancer drugs have the highest rate of first-cycle approval, data show

Rank	Disease Area	First Cycle Approval Rate	Total NME Applications
1	Oncology	72%	61
2	GI	69%	13
3	Infectious Disease	59%	39
4	Hematology	57%	7
5	Other	50%	8
6	Metabolic	47%	45
7	Ophthalmology	47%	15
8	Rheumatology	43%	7
9	Reproductive medicine	40%	10
10	Urology	36%	11

Note: Success rates for NME applications filed from 2000-2012

Source: JAMA 2014;311(4):378-384; ISI Group

submission with the FDA. Also in development are Roche/Genentech's MPDL-3280a and AstraZeneca's MEDI-4736.

This is clearly borne out by the trials. In a long-term follow up from a Phase-I study of nivolumab, there was a median duration of response of 104 weeks (n=12 patients) in advanced mM. Similarly, Merck's lambrolizumab demonstated a 52% overall response rate (ORR, n=34 patients) at its highest dose in a dose-ranging Phase-I study.

Of the different drugs in development, the BMS antibody has attracted the most attention, but there is also increasing focus on Merck's MK-3475. In terms of mechanistic differences, the BMS and Merck compounds bind to the PD-1 receptor, whereas Roche/Genentech's and AZ's compounds bind to the PD-L1 ligand. Scientists have not yet been able to establish if these differences are clinically meaningful, or to start selecting a winner.

"The PD-1 pathway is the focal point of an intensely competitive pipeline race

Analysts expect that the company who develops the best understanding of its molecule's efficacy spectrum will win the day. "Since we do not know which cancers will be most sensitive to PD-1 axis blockade, the company that runs the most investigational trials will learn more about the overall efficacy across the human cancer spectrum," say Andrew Bush and Reena Khurana from SmartAnalyst.

While Bristol's candidate is regarded as the strongest contender due to the number of trials it is conducting, an early February announcement by Merck about plans to partner with a trio of other pharma heavyweights in combination therapy trials has the research and investment communities abuzz. By collaborating with Pfizer, Incyte and Amgen to investigate different combinations and by substantially ramping in-house work on MK-3475, Merck R&D chief Roger Perlmutter is betting heavily on the asset. And the firm may continue the deal spree to ensure that its crown jewel achieves its potential.

As to who will cross the finish line first and obtain approval, "BMS is ahead and has been. From a regulatory position, again, with respect to melanoma, Merck has essentially caught up to BMS; and you could make the case that they have pulled ahead in terms of regulatory timelines," according to *in*Thought's Engelsgjerd.

Engelsgjerd continues, "It is quite likely that the greatest benefit from immune checkpoint inhibitors will derive from sequential or concomitant use with other agents. Unlike PD-1 competitors Roche and Bristol, Merck has fewer internal oncology assets to play with and so this collaborative approach makes strategic sense. These partnerships, along with the initiation of the rolling BLA melanoma filing for MK-3475 announced in January, have done much to close the gap with Bristol's nivolumab."

While most of the hubbub is focused on the PD-1 pathway, there have been important developments in the world of hematological malignancies as well. Key pipeline assets that are being closely looked at include idelalisib, a PI3K-delta inhibitor, which is under development by Gilead Sciences for treatment of chronic lymphocytic leukemia (CLL); and Roche/Genentech's GDC-199, an Bcl2 inhibitor that induces apoptosis to destroy tumor cells in diseases such as CLL, non-hodgkin's lymphoma and multiple myeloma. ■

"Unlike targeted agents, immuno-therapies can provide a much longer duration of response."

—Sharon Karlsberg, *principal, ZS Associates*

8 The number of new cancer drugs the FDA approved in 2013

Source: FDA

New study reveals:

75% of U.S. oncologists would value an oncology company and its products *more* if that company did *just one thing*

Oncologists indicated that doing just this one thing would demonstrate that the company is more dedicated and has stronger leadership, more committed resources, greater innovation, more robust product pipelines, and better research. Multiple studies, including this one, have confirmed that doing this one thing correlates with increased oncologist recommendation behaviors, including trying new products, participating in clinical trials, providing additional time to company representatives, reading the company's literature, and attending company-sponsored programs.

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Engaging Oncologists
An Elusive Target

Increasing consolidation and heavier case loads have conspired to shrink oncologist engagement levels to a historic low. Experts offer some tips for reaching this elusive bunch.

It's well known that oncologists are a challenging segment of physicians to target through traditional detailing—typically all they want to hear about is data, and by the time a rep arrives to share data, they have probably already seen it at ASCO or other scientific meetings. Add to that the consolidation of oncology practices and the sheer volume of patients being seen by oncologists, and the result has been plummeting levels of engagement.

ZS's AccessMonitor demonstrates dramatic escalation in the proportion of oncologists who have become "access restricting" or "severely access restricting" between 2008 and 2013 (see chart). How then do manufacturers stay relevant as part of oncologists' information diet, and how are they to relay brand benefits?

According to Charlene Prounis, CEO and managing partner at ad agency Flashpoint Medica, "The way to an oncologist's heart is through data."

This means reps need to be armed more with a data dossier than a traditional visual aid. No fancy branding imagery, no "catchy" slogans, just the facts ma'am.

Sales training updates also need to be more frequent so that reps can keep pace with the latest and greatest information emanating from the rapidly evolving world of cancer clinical trials. Prounis also recommends that reps are provided materials and trained to have unbranded disease awareness conversations with physicians, as this enhances engagement and underscores the manufacturer's commitment.

Prounis, whose agency works on major oncology accounts for Genentech and Novartis, points out that "engaging the HCP" is moving beyond just the oncologist. The advent of personalized medicine in the cancer space means that genetic screening, which may involve tissue extraction and sampling, is a critical step in the treatment pathway.

That means companies need to broaden their focus to include other HCPs who manage the patient along the journey, such as other specialists who would actually order the tests, and/or those who would extract and/or analyze the tissue (e.g., the surgeon, pulmonologist, interventional radiologist, and clinical pathologist).

At the same time, in oncology it's critical to recognize that success is shaped less by commercial, and more by clinical strategy early on in the life of the product. Brand narratives are shaped well before FDA approval. "By the time you get to market, these products are established with the key people. You see the growth of MSLs. We are big believers in using clinical trials to engage both the HCPs and the patient advocates in a conversation," points out Mike McLinden, partner and chief strategy officer at Mc|K Healthcare.

The broader trend of practice consolidation means that companies must look beyond just targeting individual oncologists. They are now looking to add institution and practices executives to their list of targets, with some adopting a "key account manager" approach to engaging large centers.

The fact that many reps are armed with iPads is a favorable development, according to Flashpoint's Prounis, since they allow more dynamic presentations, and for reps to customize data dossiers to the specific information needs of the doc or exec in front of them.

Reps also can use their iPads to show key-opinion-leader video presentations or to immediately video link to a medical science liaison if the doctor has a question. However, iPad details require rigorous sales training so that reps can be agile and make the most of limited HCP face time.

Gamification also is being harnessed more and more in oncology as a tactic to make learning fun and competitive. Take, for example, the "Smartest Oncologist," a quiz housed on MDLinx. Each day features a new quiz, mainly on solid tumors, and allows physicians to test their knowledge vs. that of their peers. ■

Tough sell

The decline in sales-rep access to oncologists over time

Year	% Restricting	% Accessible
2008	13.82%	86.18%
2009	14.39%	85.62%
2010	25.13%	74.87%
2011	38.48%	61.51%
2012	53.62%	46.38%
2013	61.65%	38.34%

Source: ZS Associates AccessMonitor

"The way to an oncologist's heart is through data."

—Charlene Prounis, *CEO and managing partner, Flashpoint Medica*

10.4%

The amount of oncologists who were severely access-restricting in 2013, up from 1.3% in 2008

Source: ZS Associates


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The Patient Dialogue
Avenues to Engage

Success in this space depends on mastering "patient centricity." That means deep engagement with the community. But what does it mean in practice? Some suggestions for drawing the interest and participation of patients and caregivers

Being successful in the oncology space means mastering "patient centricity." That essentially means building a long-term, deep and genuine commitment to engaging patients, caregivers and other members of the patient's close community in a meaningful way all across the drug-development continuum.

How should industry be thinking about engagement—what does it mean in practice? "Engagement is working with the community, patients and caretakers, and identifying common goals between a pharmaceutical company and the people who are using or who might use their products," states April Meijer, SVP of healthcare communications firm Discovery USA, whose oncology clients include AstraZeneca, Bristol-Myers Squibb and Novartis. "It's a long-term approach, not just a one-off."

Experts say patient and community involvement needs to start at the grassroots level, from the very earliest stages of the development process. Industry, however, has big challenges in terms of achieving this early-stage interaction.

> **"Patient-centricity means building a long-term and genuine commitment**

"From my standpoint, the most critical aspect that drives patient engagement in oncology is clinical trial awareness and involvement," notes Dave Querry, president of inVentiv Health high-science agency Navicor. "But only a small fraction of cancer patients participate in clinical trials, for a number of reasons. One is lack of awareness.

"We as an industry have not extended that olive branch to get patients engaged and to pursue clinical trials," adds Querry. "There are a couple of factors standing in our way—the financial/business aspect, but also physicians are not as prominent in their advocacy of clinical trials as they should be."

Taking It to the Web

Oftentimes, the major medium through which patient engagement is occurring is the web. Online patient communities have proliferated.

"Creating virtual communities to provide content, facilitate networking and offer services not only offers benefits to the patient and caregiver, but assists the physician in providing information on the disease and drug side effects, as well as updates on new therapies," notes Gautam Aggarwal, partner at consultancy Triangle Insights Group.

Aggarwal points to the Novartis community "My CML Circle" as a good model of a pharma-backed hub that hits all of the above levers.

It's also a good reminder that being "patient-centric" is not just about the patient. Companies use the term "health care consumers" to encompass caregivers, as well as other members of the patient's support circle.

Nevertheless, patients are scarce but empowered, so the success of trials—especially small trials of biomarker-expressing patient subsets—depends on their interest and participation. Grassroots outreach/advocacy and unbranded/non-promotional disease education can help stimulate their involvement.

The reason why the pre-commercialization process is often the ideal time to engage the patient is that it helps manufacturers build a deep understanding of the patient's journey from the get-go, with an emphasis on needs identification. This understanding can drive not only the design of clinical trials and trial endpoints, but also more meaningful communications.

"Understanding the patient's experience and the journey informs how you have conversations with patients and their caretakers; with physicians; with payers and with policy makers," explains Discovery USA's Meijer.

Partnering is one way to forge early bonds. "Patient advocacy groups can be great allies in the early stages of clinical trials—pre-commercial—in both helping to participate in that conversation about what is valuable, and in getting the word out about the potential value of it," adds Mc|K Healthcare partner and chief strategy officer Michael McLinden.

Understanding and assisting in patient adherence is another avenue of engagement, especially as compa-

> **"Engagement is working with the community, and identifying common goals between pharma and the people who are using or who might use their products."**
>
> —April Meijer, *SVP, Discovery USA*

5% Amount of cancer patients who enroll in clinical trials

Source: American Cancer Society

nies launch more and more oral therapies that require chronic usage. "A lot of the progress we've made has resulted in a slowing of the progression vs. outright cure; or a progression that is multiple lines of therapy, which is augmented by customizing therapies based upon a better understanding of the disease," notes Navicor's Querry.

"You are not only thinking about the relevant population," he continues, "but also what is a respectable duration of therapy, and how sequencing comes into it. That is an opportunity for patient engagement."

Querry cites refractory post ASCT Hodgkin's lymphoma and the medication Adcetris from Seattle Genetics, which he counts as a client. "With the advent of that therapy in a disease that had no other active therapies whatsoever, you now have an opportunity where a patient can stay on an active therapy for upwards of a year.

"Educating the patient on side effects and the value of staying on a therapy for that period of time becomes very important, especially as you balance that against side effects. Because we are shifting toward chronic maintenance in cancer, making sure the patients stay engaged, understand the benefit and 'how do I proactively manage SE' is critically important. A well-educated patient is the first step."

Access is equally important. Supporting and engaging patients involves setting up financial assistance programs and copayment support to ensure access. ZS Associates managing principal Ganesh Vedarajan points out that, "With increasing payer restrictions and out-of-pocket costs, reimbursement assistance and access support is growing in importance."

Look for patient-centricity to become even more important as personalized medicine becomes a reality. That's because the success of biomarker-driven therapy, pre-commercial and commercial, is tied to encouraging patients to get the proper diagnostic screening tests. The uptake of targeted cancer drugs hinges on patients getting the appropriate up-front testing. ■

"We as an industry have not extended that olive branch to get patients engaged and to pursue clinical trials."

—Dave Querry, *President, Navicor*

Payer Considerations
In Search of Value

Customers, from MCOs to ACOs, are scrutinizing new cancer medicines as they fine tune ways to drive physician behavior, all with an eye on costs. How to establish a rapport with payers and communicate the value of drugs

Forward-thinking manufacturers are recognizing that the main customer in the oncology business has shifted from individual oncologists to large organizations: insurance companies, large institutions, governments and, increasingly, accountable care organizations (ACOs).

As these customers' priorities are focused more on cost-containment, they are increasingly scrutinizing new cancer medicines and managing the category with an eye toward optimal value.

"Payers are really paying attention to oncology drug spend," notes Dr. John Whang, co-president of Reimbursement Intelligence. "They're aware that the pharma pipeline is weighted heavily toward [cancer medicines], and they are very concerned about the budget impact of these agents."

It's not just the large purchasers that are protesting over the high cost of cancer medicines. Oncologists have taken up the mantle as well. "Although Memorial Sloan Kettering Cancer Center is not a payer in a strict sense, it's initial decision not to cover [Sanofi colorectal cancer med] Zaltrap shows that payers (broadly described as any entity that takes financial risk) are now willing to say 'no' where value isn't clearly demonstrated," notes Whang.

Surveys conducted by his company and others demonstrate that payers are increasingly applying prior authorizations, step-edits, and quantity limits in cancer, especially in categories where there are multiple options. And institutions are incentivizing their network physicians to adopt oncologist-developed therapeutic pathways as a way to standardize and optimize their approaches to certain tumor types.

"At this point, many national and some regional payers have treatment pathways targeting specific tumor types," adds Meadow Green, associate consultant, oncology commercial strategies, Kantar Health. "These pathways are designed to steer providers to a narrower set of treatment options than guidelines alone. Since many of these programs already have results reporting on their effectiveness, payers may be fine-tuning incentives/disincentives to really drive change in physician behavior."

Green says she's also seeing experimentation in formulary design. According to Kantar research, around three-quarters of commercial payers distributed their oral cancer drugs across tiers, leading to differential cost sharing. In addition, she says, some more cutting-edge plans have added physician-administered drugs to the formulary and split drugs used in the same indication across a preferred and non-preferred specialty tier.

"As therapeutic options proliferate," Green says, "we expect to see more management in oncology in terms of formulary and pathway placement as well as the emergence of coverage criteria such as step

Oncologists have pushed back on the price of cancer meds

"They're aware that pipelines are weighted toward [cancer meds], and they are very concerned."

—John Whang, *co-pres., Reimbursement Intelligence*

75%

Amount of commercial health plans that tier their oral cancer drugs

Source: Kantar Health

therapy within the prior-authorization process previously seen in other therapeutic areas,"

Manufacturers are stepping up their clinical-development strategies to meet the demands of these value-shopping customers, and are seeing the dividends. For example, according to Manu Bammi, CEO, marketing research and consulting agency SmartAnalyst, besides mortality, Germany's cost watchdog Institute for Quality and Efficiency in Health Care (IQWiG) is including assessment of morbidity in most of its evaluations.

"In its analysis of [Genentech's] Perjeta in HER2 positive breast cancer, IQWiG pointed out the absence of any evaluable data on 'health-related quality of life' and 'morbidity' (i.e., symptoms, complaints and complications)," observes Bammi. "For the prostate cancer drug Zytiga [Janssen], IQWiG indicated severe pain occurred later in the Zytiga group, where it took about three months longer for 25% of the patients to need an opiate. IQWiG argued that this effect resulted in an indication of 'considerable added benefit.'"

To adapt to this environment, manufacturers first need a firm grasp of the "value drivers" that govern both pathway designers and payers within a given oncology indication. "We've seen in our pathway research that it goes beyond simple outcomes data," says Whang.

"Payers are stepping up use of various formulary management techniques

Patient financial considerations, physician experience, strength of the outcomes or safety evidence (e.g., impact of alpha spend on perceived data quality), co-morbidities and ability to target therapies are all things that impact the decision to place or sequence products on pathways, he says.

The next priority in establishing better rapport with payers is to effectively communicate that value, not only to insurers but to the various other stakeholders including physicians, patients and their caregivers.

"This could be simply to ensure that payers are informed of new clinical data that could impact formulary placement, pathways placement, or prior-authorization criteria," says Gordon Gochenauer, director, oncology commercial strategies at Kantar Health. "Payers also want to ensure that real-world outcomes match those in the clinical trials. In some circumstances, payers may choose to rely on their own methods and their own data collected to measure outcomes rather than choosing to utilize real-world data provided by manufacturers."

Manufacturers, he adds, can also develop programs that payers could encourage patients to use, such as disease education, drug adherence or compliance programs, survivorship programs, case management, benefits management, and prescription-fulfillment programs. "These programs can overlap with payer goals, thus providing the manufacturer with a favorable profile with payers and patients."

While in the past, pharma sales reps have been focused on offering clinically oriented data to physician customers, the industry sales model is transforming from just the PSR to also include account managers targeting large customers. The goal is not about driving the features and benefits of individual products, but more about helping customers satisfy their quality improvement goals.

Going forward, the trend toward more individualization of cancer treatments to the specific genetic characteristics of each patient's tumor is a welcome development from the standpoint of payers and institutions, creating a more predictable link between drug delivered and favorable outcome achieved. ■

"We expect more management in oncology in terms of formulary and pathway placement."

—Meadow Green, *assoc. consultant, Kantar Health*