A special compilation of milestone moments from the history of our first 50 years
IN CELEBRATORY ISSUES SUCH AS THIS, there’s an unfortunate tendency to devote an inordinate amount of attention to one’s own achievements. You know: Look at us. We’ve been here for 50 whole years. That’s, like, a triple eternity in publishing. Bask in our uninterrupted presence!

The only thing less interesting than reading a self-related history of that sort, of course, is self-relating that history. To that end, we present you with this eBook, which encapsulates our Milestone Moments in each of six broad categories: Provider, Media, Marketing, Patient, Payer, and Regulatory. You’ll find reviews of the first DTC ads, the rise of payer power, and the iconic marketing of Viagra, whenever possible told by the people involved. You’ll also get the first glimpse — outside the halls of Merck’s corporate campus, that is — at the pharma giant’s trove of original artwork, much of which made its way into company promotion.

The hope is that by reviewing some of this industry’s highest-profile successes and struggles with fresh eyes, we can mine them for insights that will serve it well in the years ahead. — Larry Dobrow

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THE FIRST

MILESTONES: PROVIDER GIFT BAN

THE DAY THE TCHOTCHKES DIED

For some people in the industry ecosystem, the appeal of promo nicknacks endures.

BY REBECCA MAYER KNUTSEN

For years, pharma helped keep the makers of Lipitor pens, Prevacid golf club head covers, and other promotional items in business. When the Pharmaceutical Research and Manufacturers of America imposed a voluntary ban in 2009, no one expected such tchotchkes to have a collectible afterlife.

The decision to enact the ban was a no-brainer. PhRMA was not alone in sensing a need to clean up the industry’s image by addressing the ethics of providing an array of branded gifts to physicians. Gimmicky marketing mementos like Post-it notes and pens may have seemed harmless enough, but the prescribing influence they carried came into question.

“These items were in view and intended to keep specific drug names uppermost in physicians’ subconscious. And it worked,” says Dr. Adriane Fugh-Berman, an associate professor in the departments of pharmacology and physiology and family medicine at the Georgetown University Medical Center and director of PharmedOut, a Georgetown research and education project that, per its website, “promotes rational prescribing and exposes the effect of pharmaceutical marketing on prescribing practices.”

These relics of the past have a certain value for those on the hunt. One eBay seller hopes to fetch $20 for a blue pill-shaped Viagra promotional clock that doubles as a business card holder. And those golf club head covers — in the shape of a stomach, designed to somewhat subtly remind docs of Prevacid’s utility in treating heartburn — still make occasional appearances on golf courses.

Low-brow high jinks?

“Many physicians thought the ban was silly, but that’s because they were — and are — unaware of the effect of small gifts on creating a sense of obligation,” Fugh-Berman says.

According to Dr. David Lee Scher, a cardiologist and digital health technology consultant at DLS Healthcare Consulting, some physicians were upset when the tchotchke well dried up, but not for the aforementioned reasons.

“It wasn’t the inability to obtain the gifts. Rather, it was the loss of a line of communication to the company about product education,” he explains. “Pharma must have thought the tchotchkes translated into prescriptions, but personally, those things never influenced me.”

The physician–sales rep line

Scher, however, contends that the ban had a broader effect than intended, unintentionally creating regulatory barriers to pharma–provider communication. When the promotional items became obsolete, so too did many of the field representative calls. “I no longer had a person to call when I needed information about new and existing drugs,” he shrugs.

On the pharma side, the ruling may have been a blessing. Ditching the freebies was a way for the industry to respond to public scrutiny, plus pharma manufacturers stood to save large amounts of money by halting production of the items.

Next target: CME?

With the eradication of industry gifts to physicians, gone too is the concern of subtly influencing professional judgment in the care of patients. Or is it? Criticism of CME and DTC promotion has been gaining traction.

Some wonder why the tchotchkes are still a topic of conversation in 2016. “While pens, pads, and the like were common in the industry, their absence has not been a big milestone in the modern history of medical marketing,” shrugs John Kamp, executive director of the Coalition for Healthcare Communication.

Much more important in Kamp’s mind was the FDA decision in 1997 to enable widespread broadcast DTC advertising — and the subsequent failures by then Rep. Henry Waxman and Sen. Edward Kennedy to effectively ban it via legislation. “The controversy over DTC advertising may not be over,” Kamp says.

What sacrifice?

Those in the dissenter camp look at the gift moratorium as little more than a Band-Aid atop a gushing wound. To hear Fugh-Berman tell it, pharmaceutical companies jettisoned promotional items without much thought — and at least in part to preserve their influence in other, less obvious venues, such as CME.

“It was a sacrifice, but it was a sacrifice of the least-favorite child,” Fugh-Berman points out. In turn, pharma marketers focused on more covert forms of promotion, like disease-awareness campaigns and DTC promotion.

Along those lines, the voluntary PhRMA moratorium, the Accreditation Council for Continuing Medical Education’s commercial support standards, and the FDA guidance on industry-supported education all emphasize the need to separate promotion from education. “Each regulation reinforced the importance of independent education and creating a safe space for learning,” notes Dr. Graham McMahon, ACCME’s president and CEO. “It was, and is, in the best interest of all concerned.”

McMahon insists that accredited CME will continue to evolve and meet the changing needs of its learners, embracing best practices and engaging physicians in high-quality development activities into the foreseeable future. “Our learners’ educational needs will drive their skills, not promotional or marketing materials that may have had influence in the past,” McMahon says.
When one discusses the creative giants of medical advertising’s past half century, talk usually turns to artists enshrined in the Medical Advertising Hall of Fame — Ernie Smith and his iconic depiction of the “Benadryl fathead,” say, or Sal deRouin and his canny use of construction hard hats to connote product attributes (the safety of heart drug Cardizem). Such discussions might also reference any number of marketing agencies, both living entities and shops subsumed into a larger organization via merger or acquisition, and the path they paved by pushing reluctant pharma companies to broaden their aesthetic horizons.

One of the names less likely to pop up in such conversations is Merck. Granted, few pharma giants have established themselves as Rx Club mainstays, or even endeavored to do so. But there has always been a sense that, more than its peers, Merck had less interest in artistic exploration than it did in meat-and-potatoes message conveyance. Which, obviously, is fine — marketing effectiveness has never hinged on artistic virtuosity. Nobody’s demanding that an ad for Zontivity must deliver a master class in sketchwork with compressed charcoal.

The problem is that this perception of Merck’s creative bona fides is, well, wrong. The unveiling of hundreds of images created at the company’s request by artists like Norman Rockwell, Dr. Paul Peck, and Joel Nakamura suggests that Merck might have been among the pharma world’s most progressive-minded organizations, at least when it comes to cultivating museum-grade artwork. Taken collectively, the freshly rediscovered images — thousands of them — serve as a history of the industry’s artistic evolution writ small.

Industry support declines

Peter Plante, creative director of Merck Creative Studios and lead of Merck Archival Services, does not seek credit for this. “If you paint me as an ‘industry legend,’ I’m going to get laughed out of this building,” he says. “I’m just a guy who’s had some unique experiences in his career.”

At the same time, Plante’s off-the-clock efforts served to liberate the Merck artwork from back-office obscurity. “I curated a lot of it at my house on Friday nights because I needed room to sort it,” he says. “I just couldn’t bear the thought of all this
beautiful, important work being thrown out or left in some room collecting dust.”

Plante was assisted on his quest by two other Merck execs who share his interest in preserving a neglected part of its historical record. “We call ourselves the Monument Men of Merck, even though it’s me and two women,” he deadpans. Their expeditions paid off in the form of finds like an original Rockwell. “Nobody even knew it was on the wall,” he says. Indeed, it’s quite a stash. Nearly 73,000 creative assets have been digitized. It took eight tractor trailers to transport the 4,100 linear feet of physical assets to Merck’s formal archive, now located in what a rep describes as a “disaster-prepared, geosecure warehouse that exceeds national archival standards.” The decision to relocate the artwork to a fortified facility may or may not have been prompted by a fire that claimed much of the artwork Merck inherited on acquiring Schering-Plough, in 2009. Only those works with titles commencing with the letters A through C (hello, Claritin) survived.

To browse the Merck archives is to be reawakened to a part of the industry’s creative past that informs its present. The works date to the 1930s and ’40s, when Merck formally established an in-house creative group. In the 1960s, the group was expanded to include a fuller complement of on-site art directors. This decision explains why Merck was able to devote considerable resources to medical illustration and other fine artistry (it had people on hand who made such projects a top priority). It also might explain why Merck’s creative reputation failed to keep pace with the caliber of the work it produced: Many top agencies, Plante believes, declined to work with Merck, knowing that its in-house artists and art directors would have final say on all things creative.

**Museum-grade artwork**

If this proved a handicap in any way, it’s hard to tell from the artwork itself. Merck’s artistic glory era began in 1959, when it entered into an exclusive agreement with esteemed medical illustrator Peck. The relationship ultimately produced more than 500 pieces. Similarly fruitful was the collaboration with Nakamura, whose creations on tin fueled the drugmaker’s global Maxalt campaign for more than a decade.

“When you show somebody the work, [the reaction is], ‘Oh, wow!’ It’s awe,” Plante says. “The vasculature within the hearts, the nerves pulsing through arms and hands — who’d have thought colons could be beautiful? But they are.”

Plante believes the elaborate nature of much of the work in the Merck archives presaged the current digital era, especially in animated and 3-D renderings of products, processes, and procedures. As for what people will take away from the revelation of the art and advertising cache, Plante hopes it will motivate them to extend that legacy into the future. His one worry? That rights-related issues could delay sharing the artwork.

“I ask around — ‘Oh, somebody at that one boutique agency in Philadelphia can get you permission.’ But all those agencies got blown up or merged or whatever. I wouldn’t even begin to know where to look for the contracts,” Plante laments. At the same time, he remains thrilled — as both artist and marketing professional — that Merck saw the value in saving and securing the work for posterity. “[The artwork] brought prestige to the company and helped cement relationships with customers. It brought value,” Plante says. “It tells us so much about where we’ve been and where we may be going.”
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The inside story on a campaign for the ages, as told by the individuals who worked on it.

BY LARRY DOBROW

When Pfizer launched Viagra in 1998, it did so with eyes wide open about the immediate impact the drug would have — on patients, of course, but also on physicians, the health media, and purveyors of late-night chuckles. What the company may not have anticipated was the longer-term influence that Viagra’s wild success would wield on pharma marketing as a discipline.

“Right from the outset, it felt as if we were working on a big brand,” recalls Michael Sanzen, then VP, group copy supervisor at Cline Davis & Mann, who worked with VP, group account supervisor Ken Begasse on a broad range of HCP- and patient-communication tasks during Viagra’s infancy (the two would cofound Concentric Health Experience in 2002, where they continue to work today).

“It was one of the first times in the pharma space where we were really ideating on what a brand needed to be based on the customer perspective, not solely on the product perspective,” Sanzen says.

McCann HumanCare SVP, group creative director Doug Welch, who co-led his agency’s successful pitch for a big piece of Viagra business in 2004, agrees. “It felt as if we were in the middle of something big,” he says. “Would we be quite where we are today in the canard with which we discuss sensitive conditions? I honestly doubt it.”

While Pfizer declined an interview request, a handful of marketers who worked on the campaign during its early days were happy to take a trip down memory lane. Without further ado, here are the seven ways that Pfizer’s marketing of Viagra proved transformational — for Pfizer, sure, but also for the business as a whole.

1. It provided the blueprint for medicalizing a supposed lifestyle condition. Ultimately, this is Viagra’s great legacy from a marketing perspective. Among Pfizer’s greatest concerns during the run-up to launch was that Viagra wouldn’t be taken seriously enough as a medication and that the media would downplay its medical utility in favor of cheap boner-pill gags. The brand and marketing teams realized that such a perception could limit the drug’s impact, both on the lives of needy patients and, well, the bottom line.

The solution was a focused educational effort that began well before Viagra hit the market. Ultimately, the effort went down in pharma marketing lore as the first and most effective medicalization campaign.

“We had to give physicians a reason to have a conversation about this,” recalls Begasse. “That meant linking [erectile dysfunction] to the things physicians were traditionally concerned about — diabetes and cardiac conditions in particular.”

That same message was emphasized in Viagra’s media strategy. “We knew the nature of the condition was going to lead to challenges,” says Lisa Stockman, then a team leader at Chandler Chicco Agency and now president, communications at inVentiv Health. “You can’t totally get away from that, but we tried to show the impact of ED on men, in terms of emotional well-being and depression, beyond the effect on their sex lives.”

2. It created a new therapeutic category. Well, not really: Impotence, as it was then known, didn’t suddenly emerge in the late 1990s. But by the time Viagra showed up, impotence was thoroughly stigmatized, as both a condition and a word.

By recasting impotence as “erectile dysfunction,” Pfizer and its marketing partners dodged this toxic attitudinal predisposition. “We had the chance to engage on different terms,” Stockman says. “No
matter what anybody said or did, ‘impotence’ had little chance of being thought of as a medical condition. ‘Erectile dysfunction’ did.”

3. The creation of that new category enabled more candid conversations with physicians. The shift from “impotence” had a secondary benefit of appealing to physicians. As hard as it may be to believe with 18 years of hindsight, Viagra was a tough sell for the physician audience. Yes, it had sexuality as part of its brand promise, but it was designed to treat a physical condition that many doctors believed was in no small part psychological in nature.

“It was kind of a hidden barrier,” Sanzen says. “There was so much taboo around discussions with patients about sex and relationships. [Physicians] didn’t think it was their place to have that conversation. Maybe the language choice gave them a little more of an opening.”

4. It ushered in the celebrity spokesperson. Longtime senator, former presidential candidate, and honored war veteran Bob Dole wasn’t the first celebrity to endorse a pharmaceutical product in the DTC era. But when he appeared in a Viagra commercial in 1998, he encouraged pharma to aim high.

By addressing the issue head-on and personalizing it — something, it’s worth noting, that Viagra’s early-2000s army of NASCAR endorsers never did — Dole injected a note of humanity into the conversation around the drug. This became the blueprint for all celeb campaigns that followed: Find a celebrity who has been directly affected by a disease or condition (Dole was in the wake of his treatment for prostate cancer), then let him or her testify.

“I was afraid, but it was important for us,” Stockman says. “There was so much taboo around these topics. America was a little more conservative back then — and the media certainly was,” Stockman continues. “This marked a pivot point for the coverage of pharmaceutical products. Now the media will talk about pretty much anything.”

6. It freed drug marketers to rethink their sales materials. As much as early Viagra marketing focused on breaking down patient reluctance toward treatment and conversation, Pfizer knew that such an effort wouldn’t pay immediate dividends. "It was the first time that a medical product made that leap into pop culture and the family living room conversation,” she notes. “Before, there wasn’t any acknowledgment that you’d take a medicine for something that might affect you in your prime. ‘The thinking was ‘medicines are things that old people take.’”

Nobody on Team Viagra was surprised when the drug made an appearance on the cover of Time. “Before Viagra, there wasn’t much discussion on the nightly news about these topics. America was a little more conservative back then — and the media still reel stats off the top of her head: two billion impressions within a month and 865 million audience impressions within 48 hours of FDA approval.

That’s why she and other individuals who worked media and PR on Viagra’s behalf sat down with physicians and scientists well in advance of its debut. Their counsel, particularly as it pertained to the unexplained medical and psychological impact of ED, proved invaluable.

“Before Viagra, there wasn’t any acknowledgment that you’d take a medicine for something that might affect you in your prime. ‘The thinking was ‘medicines are things that old people take.’”

Pfizer conveyed information about Viagra in Voices, a custom publication. In it, sports and entertainment personalities weighed in on the importance of men taking charge of their health. Voices also dispelled myths about erectile dysfunction.

“Men could pick [Voices] up in the office and the other patients wouldn’t necessarily recognize it as a Viagra piece,” Sanzen says. “It was a targeted, undercover way of getting to that patient.”

Team Viagra similarly attempted to rethink the typical drug starter kit, which hadn’t evolved much beyond its initial iteration of three pills in a box. While the Viagra kit derived some packaging inspiration from the Z-Pak, it departed from the norm in everything from the nonclinical language it employed to the number of pills it contained.

“We recognized that for these men, who had been suffering in silence for a long time, the first experience was everything,” Begasse recalls. “Clinically, we knew it might take a few tries for them to get the full effect — so by adding more pills [to the kit], it wasn’t that we were giving away free experiences. We did whatever we could to make that first one a good one.”

7. It made a whole lot of careers. Stockman and the Concentric duo of Begasse and Sanzen downplay the effect the work they did early in their professional lives on Viagra had on everything that followed. But they acknowledge the immediate increase in profile enjoyed by many of the individuals who played a leading role in the early days of Viagra marketing.

“Well, I’m still here,” Stockman says with a self-deprecating laugh. “It put Chandler Chicco on the map. Between Viagra in 1998 and Celebrex in 1999, we came to be known as the ‘blockbuster’ agency. Whether or not that was accurate, it wasn’t a bad thing to have out there.”

Sanzen feels the same way about his work on Viagra and its effect on everything that followed. “Creatively for us, it was a lifetime’s worth of experience in a matter of a couple of years. We walked out of there feeling as though we’d worked with 10 brands over the course of 15 years, rather than one brand over the course of two,” he says. “We’re probably still drawing on that experience now. It’s rare for a single brand to give you that much fuel.”

Begasse agrees, adding, “You know what Malcolm Gladwell says, that once you do anything for 10,000 hours you become an expert? Well, we amassed 20,000 hours of experience on that one brand alone. Add [his and Sanzen’s work on] Lipitor to that, and you couldn’t write a better script for two guys who were motivated and had ambitions in this industry.”
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THE FIRST Liz Moench was there at the very beginning. At 23, she joined Boots, a Louisiana-based upstart known to few people outside the pharma universe. She knew relatively little about the industry herself. During her job interview with John Bryer, then Boots’ president, she innocently asked why patients weren’t viewed as the company’s target customers. That wasn’t the type of question that pharma marketing execs were asking back then, though, in retrospect, it’s the type of question that should’ve been asked far sooner. “It was radical to come in from the outside,” Moench says, referring to her previous gig in TV advertising. “And it was radical to have a senior executive who was really open-minded in his thinking. [Bryer] was a real maverick.”

Within months, Moench had played a leading role in creating the healthcare industry’s first DTC TV ad. Here’s her story, as well as those of two other DTC titans, Francis Gace and Steve Andrzejewski.

1983: THE FIRST DTC SPOT
Moench’s ad, for Rufen, an anti-inflammatory drug, aired in Tampa on May 19, 1983. It targeted an audience that was a “good representation of the demographics of the U.S. at the time,” Moench recalls: existing patients who already knew about ibuprofen. The spot made no representations that it was intended for treating arthritis.

Per the advice of the Boots legal team, the ad focused on pricing, with Bryer himself noting that Rufen was 20% cheaper than competitor Motrin. “We didn’t say what [Rufen] was for. We didn’t talk about it being better than another drug, or any of its benefits,” Moench continues. “By running a price ad, we didn’t need to go into the issue of the package insert.”

Boots timed the Rufen ad to coincide with a front-page marketing feature that ran every Thursday in The Wall Street Journal. The drugmaker gave the newspaper an exclusive interview about the ad, for reasons that transcended marketing. “That was our way of notifying the FDA,” Moench reveals. “We didn’t tell them the date we were launching. We’d had our meetings with them, but they wouldn’t tell us if they would take action or not. And the law had no specific regulations governing consumer or DTC advertising, which is why we ran a newspaper [ad] with the full package insert.”

Within two days of the ad’s airing, the FDA sent Boots a cease and desist letter. It also imposed a two-year moratorium on DTC advertising using brand names. But the cat was out of the bag.

Four years later, as the executive director of public affairs at Ciba-Geigy (today part of Novartis), Moench helped recruit what is thought to be the first celebrity spokesperson for a prescription drug: legendary New York Yankee Mickey Mantle, who spoke on behalf of prescription pain relief drug Voltaren.

“We had to meet Rep. John Dingell, who was part of the oversight committee looking at marketing practices in the pharmaceutical industry, because Mickey got onto Today,” Moench recalls. “When Mickey thought the interview was over, he said, ‘You know, this drug works great for hangovers.’ So millions of people heard this. I’m sitting in the holding room going, ‘My career’s over.’”

1992: THE SUPER BOWL
In the wake of the FDA’s two-year moratorium on branded DTC advertising, the industry was skittish. Bold moves were few and far between — until Marion Merrell Dow launched the industry’s first Super Bowl ad, in January 1992, featuring smoking-cessation patch Nicoderm.

“We knew in the Super Bowl audience, which was going to be anywhere between 80 and 100 million eyeballs, there would be a fair number of smokers,” recalls Francis Gace, cofounder of...
Lewis & Gace, the agency that worked on the ad. “Plus any ad on the Super Bowl got talked about. We could anticipate a fair amount of word of mouth, particularly if we were the first on the market.”

To skirt the requirement of a time-consuming full disclosure, which included warnings, side effects, and benefits, the drugmaker could only name the product and say what it was, not show the patch itself. The spot featured two men taking an escalator at an airport. One man said, “Nicoderm.” The other responded, “Yes, it’s a patch.”

“That’s about all we could say in the entire commercial,” Gace adds. “But we figured that we’d already marketed Nicorette. The name similarity was close enough. We figured it would be clear to anyone who was watching that we were talking about smoking cessation.”

The ad cost about $1 million for 30 seconds of airtime. Habitrol may have outspent Nicoderm in detailing ($34 million to $19 million), sampling ($9.6 million to $4.5 million), and consumer advertising ($34 million to $23 million), yet Nicoderm became the number one prescription brand among smoking-cessation patches.

1997: DTC BUDGETS SKYROCKET

In 1997, the FDA issued draft guidance allowing pharma companies to advertise on TV without the brief summary that took up so much print space as long as they directed viewers to a magazine ad, a toll-free phone number, or a website for such information.

Schering-Plough, which manufactured allergy treatment Claritin, jumped on the opportunity (Schering was acquired by Merck in 2009).

With its renowned Blue Skies campaign, created by CommonHealth’s Thomas Ferguson Advertising, the marketing team upgraded from unbranded reminder ads to branded spots. Blue Skies evolved into a multichannel campaign that included radio, print, and TV ads, all advising consumers to “ask your doctor about Claritin.”

“A lot of people were asking, ‘Is this something you should do or not?’” says Steve Andrzejewski, who worked on that launch as VP of marketing for S-P. “‘Ask your doctor about Claritin,’ without claims, raised awareness of the name Claritin and the number one question from people seeing the ad was, ‘What is Claritin?’ It ended up educating customers that there are alternatives that wouldn’t make them sleepy.”

2016: THE EVOLUTION OF DTC

Looking back at the evolution of DTC advertising, Moench, now president and CEO of MediciGlobal, reckons that the groundwork for change was laid in the 1980s. “Back in the ’70s, patients did what doctors told them,” Moench quips. “In the 1980s, environmentalists fueled change.”

To help low-income and minority communities situated near factories and landfills, the environmentalist movement pushed for the Emergency Planning and Right to Know Act of 1986, designed to hold corporations accountable for the release of toxic chemicals in populated areas. During the same period, AIDS activists sought to involve patients in the regulatory process, HMOs emerged to allow consumers to choose their health plans, and the notion of a patient’s right to understand gave birth to patient package inserts (PPIs), Moench explains.

“So you had these four movements — AIDS, DTC, HMOs with choice, and PPIs with understanding,” says Moench. “And that’s now been picked up in the 2000s by rare-disease groups. We talk about patient-centricity now, but it was happening in the ’80s.

“Today’s ads are lifestyle-based and aspirational,” she continues. “There seem to be a lot of themes about being with family, being able to do things that are active, being able to function at your job.” Celebrity spokespeople continue to be widely used, but Andrzejewski, now an adjunct professor of health economics at NYU’s Stern School of Business, notes a recent rise in the use of animation and caricatures.

All three execs point out, with some degree of amazement, how deeply DTC ads are now woven into the fabric of industry marketing.

“In the days of Rufen and Nicoderm, [ads for] Viagra and similar products were probably far from anyone’s mind,” Gace says.

Adds Andrzejewski, “Now there’s a higher comfort level on the pharma company side and there’s a clearer path of what to do with the FDA.”

At the same time, the DTC space has gotten crowded. And much to the consternation of TV advertising loyalists, budgets are now spread across a range of channels.

“In the past, there weren’t as many companies involved, especially in TV advertising,” Andrzejewski notes. “Today, getting the message to the intended audience is much more important because there are so many messages out there.”

2017 AND BEYOND

The value of DTC advertising continues to be a contentious topic. The AMA called for a ban on DTC advertising of drugs and devices in late 2015, linking it to inflated costs. More recently, a New York Times op-ed and a JAMA editorial criticized Bristol-Myers Squibb’s DTC ads for cancer med Opdivo, characterizing them as misleading.

DTC boosters say that the ads, along with social media, have helped patients become better informed while allowing them to play a more active role in their health decision-making. But Moench notes that DTC advertising is not as patient-centric as it should be.

Similarly, Andrzejewski says more effective hyper-targeting is critical to keep patients engaged. “Healthcare plans are playing a bigger role, and those systems are going to have something to say, so it’s important for people to be very targeted,” he explains. “Once you have the demographics, it makes the advertising spends that much more efficient because you can target them that much more specifically.”

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Some time in the late 1990s or early 2000s — neither the internet nor print sources agree on a specific year — one marketer, or perhaps many, came up with the idea of offering patients a card that would give them discounts on their co-pays for Rx drugs. The adoption of co-pay cards back when they were called “consumer cards,” “point-of-sale cards,” and “100% co-pay cards,” per a 2002 Kaiser Family Foundation report, was tied to the introduction of tiered formularies that encourage the use of low-cost generic drugs with low co-pays and seek to slow interest in higher-cost branded medicines.

Fifteen years later, it’s no wonder that patients, facing high rates of sharing costs, are in favor of co-pay cards — and that payers, tasked with footing the bill, are not. Drugmakers spent $7 billion on co-pay assistance programs in 2015, up 30% from 2014, according to data from IMS Health/Amundsen Group.

“While drug co-pay coupons may appear to help consumers, that’s not actually what they’re designed to do,” reads a July blog post by America’s Health Insurance Plans, the health insurance industry’s lobbying arm. “What drug co-pay coupons really do is keep costs high for everyone.”

The popularity of these cards has exposed the increasingly high rates of patient co-pays and co-insurance. This put payers, still on the hook for covering negotiated product prices, on the defensive. To stem rising prescription drug costs, PBMs have responded in kind: They have recently begun to lean heavily on tiered formularies, prior authorization requirements, and, more recently, formulary exclusions.

“These co-payments and co-insurance rates have changed dramatically,” says Ed Schoonveld, managing principal and leader of the market access and pricing practice at ZS Associates. “Many insurers and PBMs put more cost reductions in place and [required] more paperwork to make it hard to use these expensive options.”

The widespread use of co-pay cards highlights the ongoing tension between drugmakers and payers tussling over value. To make a long story short: Payers are now in charge, and it doesn’t look as though that is going to change anytime soon.

Pharmaceutical products may have once been placed on a pedestal marked “innovative” and “lifesaving,” but drugmakers are now struggling to keep even the newest, most-innovative therapies on formularies. As a result, they are turning to big data to reinforce the value story of their products as they market them to a handful of very powerful PBMs and health insurers.

“We in the U.S. have got to get to a different model of healthcare,” says Dr. Steve Miller, chief medical officer at Express Scripts, which covers 85 million people. “Right now, we’re paying Ritz-Carlton prices for Motel 6 services.”
The passage of the Affordable Care Act did more than provide insurance to millions of previously uninsured patients and new incentives to encourage a move from the traditional fee-for-service model to a fee-for-value system. It also led to a wave of consolidation among industry players.

**Continuing Consolidation**

Every major part of the healthcare industry — pharmaceutical companies, insurance providers, PBMs, makers of medical devices, hospitals, physicians’ groups — has undergone significant consolidation, as each sector attempts to gain the upper negotiating hand. For instance, Express Scripts, CVS Caremark, and UnitedHealth Group’s OptumRx — the three largest PBMs — now control about 75% of the market, putting them in a position to demand rebates on the drugs they cover.

That same consolidation trend has altered the landscape for commercial insurers as well. Four of the five largest commercial insurance companies in the U.S. — Aetna and Humana, and Cigna and Anthem — are attempting to merge in two separate deals, a move that in July raised Justice Department concern about competition.

What the payer consolidation trend has done is create pricing transparency, said Kim Wishnow-Per, president of McCann Managed Markets. “They could see what other payers were paying,” she says. “That started to enable them to have control over the cost of drugs.”

Finding new ways to control drug costs has become increasingly important, especially now that the drug industry has cycled out of a sluggish R&D period and into one that is bursting with Phase III trials and first-in-class product launches.

There are now 7,000 drugs in clinical development worldwide, 70% of which are first-in-class medicines, according to PhRMA, the drug industry’s lobbying arm. Novel therapies that treat diseases like lung cancer and hepatitis C, which were previously hard to care for, are increasingly becoming the standard of care.

When Gilead Sciences launched Sovaldi, its game-changing hepatitis-C cure, in 2013, its decision to charge $84,000 for a course of treatment — that translates to $1,000 a pill — took a simmering debate about drug prices from the pages of medical journals and turned it into a national conversation about how drugs are priced.

It was then that Express Scripts famously declined to put Sovaldi on its formulary, choosing to wait for AbbVie’s Viekira Pak to receive FDA approval a year later.

“That was a really remarkable moment,” Schoonveld says.

That moment also served as a warning to other drugmakers. Insurers and PBMs would no longer cover even the most-innovative drugs if they exceeded certain price points and if the outcomes didn’t match the expectations of payers.

PBMs have taken that thinking one step further, starting when Express Scripts introduced exclusions from its formularies. Traditionally, PBMs gave certain drugs non-preferred status, but rarely did they exclude coverage of a drug. But in 2017 CVS Caremark, the second-largest PBM, plans to exclude 155 drugs from its formulary. Express Scripts plans to exclude 85.

“The industry needs to make it clear to a broad set of stakeholders, including payers, that they can demonstrate the value of the innovation they bring forward,” Schoonveld says. “That is more key than ever in today’s environment.”

As payers have developed new strategies to crack down on high-priced drugs, pharmaceutical companies have realized that market-access expertise is crucial during a product launch. Not surprisingly, they have moved to add many such experts to their brand teams. “Companies are looking at their structure,” Wishnow-Per says. “That integration is happening, and they recognize that influence and how it affects their brand.”

**Let’s Make a Deal**

In addition, some drugmakers are starting to collaborate with payers to test new payment models. Cigna has inked 10 risk-sharing reimbursement models, starting with Merck’s diabetes drug Januvia in 2009. More recently, Cigna has completed deals with Novartis for Entresto, its heart-failure drug, approved in 2015; for Harvoni, Gilead’s second hepatitis-C drug; and for Sanofi’s Praluent and Amgen’s Repatha, a pair of competing PCSK9 inhibitors that came to market within a month of each other.

Cigna, like many other insurers, has started to test new reimbursement models with healthcare providers, as well as drugmakers. According to Christopher Bradbury, SVP of integrated clinical solutions and specialty pharmacy at Cigna, the greater the alignment between “the various stakeholders in the delivery system, the better off we’ll be.”

The move toward value comes as a number of new cancer drugs are expected to be approved by the FDA. The launches of Bristol-Meyers Squibb’s Opdivo and Merck’s Keytruda, both immuno-oncology drugs, and Pfizer’s breast-cancer drug Ibrance have already caught the attention of physicians seeking new ways to treat their patients. The new drugs are both powerful and pricey. Opdivo, approved last year, costs $150,000 for the first round of treatment; it generated $942 million in sales in its first year on the market. These and other new cancer drugs are “going to drive an acceleration of this value-based discussion,” Bradbury says.

Still, the pathway toward a value-based system is not well defined and will present a host of challenges for both payers and drugmakers.
FDA RISING

Back in the 1960s and 1970s, when the agency concerned itself more with the “F” than the “D,” its influence was only a fraction of what it is today. How did we get from there to here?

BY KEVIN McCAFFREY

To hear individuals who put in time at the Food and Drug Administration in the late 1960s and early ’70s tell it, today’s healthcare execs and observers wouldn’t recognize the “tiny” and “sleepy” unit it once was. But for those who wonder how the FDA evolved into the almost impossibly influential force it is today, the answers lie in a transformational decadelong period in which the organization started to throw its weight around. In doing so, it laid the foundation for the greater transparency in the drug-approval process and patient communications now taken for granted.

Take it from Wayne Pines. As chief of consumer education there during that era, he recalls that among the FDA’s highest-priority projects were the dissemination of information about the possible effects of caffeine in pregnant women and attempts to ban red food coloring and an artificial sweetener called saccharin.

“The ’70s were a transformational era for the FDA,” Pines says. “It propelled the organization from a tiny agency into the front-page agency that it is today.”

Pines recalls that the agency’s ambitions were fueled in part by external criticism. The barbs that stung most sharply were ones suggesting a certain indifference on the FDA’s part, that there was a “drug lag” — that it was delaying the approval of drugs that were already available overseas.

The problem was one of optics, Pines notes. “The drug-approval process was nothing like it is today. It was very secretive back then,” he says.

So the FDA created public advisory committees. Not only do they allow for more transparency vis-à-vis the public about drug approvals (and denials), but they also allow different voices to be heard. At the same time, the FDA has not wavered in its commitment to involve patients in the drug-approval process.

During the late 1970s and early ’80s, the agency laid the foundation for such efforts. “Back in the ’70s, drugs were sold by sales reps or via advertising in medical journals,” Pines recalls. When the FDA embraced its responsibility to bring new drugs to market, it opened marketing doors: “From a marketing standpoint, it was the beginning of promoting drugs.”

That patient-marketing push began with brochures. The first, which debuted in the early 1970s, conveyed information about the then-novel topic of oral contraceptives. In many ways, this represented the first real outreach to patients about new treatments.

With these brochures came the first package inserts. In 1968, the FDA mandated that isoprenaline contain a warning note explaining risks about excessive use. In 1970, the FDA required makers of oral contraceptives to include information about specific risks and benefits.

Patient information

“Now it’s commonly accepted that patients are entitled to information about the drugs they take,” Pines says. “But in the 1960s, nobody knew what drugs were being prescribed. In the past 50 years, we’ve gone from zero information for patients — and zero involvement by them — to DTC ads.”

Fast-forward 50 years and the debate over how to communicate with patients rages on. In 2009, on a single day in April, the FDA issued 14 warning letters to drugmakers over the “one-click-away” rule, which really wasn’t a rule at all. It was more an unwritten admission that if risk information was only one click away from a drug’s online promotion, it fell within regulatory parameters.

“The situation remains unsettled. “There are still questions about the one-click-away rule,” John Kamp, executive director of the Coalition for Healthcare Communication, says.

“The FDA, at least in some people’s view, refuses to accept the reality of new media,” Kamp continues. “You can’t treat the internet like it’s a print page in a journal. We all know how to use links. The FDA should recognize that.”

So where does the FDA go from here? Peter Pitts, who was the FDA’s associate commissioner for external relations from 2002 to 2004, believes the agency needs to do a “better job of leading than following.” If it doesn’t, the FDA risks adding further ambiguity to a process that many marketers already believe has too many gray areas.

“Social media, off-label communications — the FDA has been ambiguous in its pronouncements,” Pitts says.

The way forward

Pines says that although the FDA has a record of making “sound scientific decisions with regard to products and risk based on the available data,” it has not been timely in its issuance of new guidelines.

“The agency needs to update its policies with regard to the regulation of marketing communications,” he explains. “We’ve had a number of recent court cases that have raised fundamental questions about current regulatory standards. The agency has been trying to deal with it, but needs to do so in a more timely fashion.

“It’s ironic that patients have access to so much misinformation on the internet,” Pines continues, “yet the companies that know the most are the most heavily regulated about what they can communicate.”
PARTNER PERSPECTIVES

Congratulations to *MM&M* on 50 years!
My partner, Michael Sanzen, and I feel so fortunate to have been a part of two significant culture-shaping launches that redefined our industry, Lipitor and Viagra. Both were pioneering brands in the pharma space, where we ideated the brand experience based on the customer perspective, not solely on the product perspective.

They marked amazing inflection points in our evolution as an industry to be more customer-focused, and it changed the trajectory of our careers, as well. — Ken Begasse, founder and CEO

There was a time when healthcare marketing was too new to even have a moniker. Those wise enough to foresee its potential had little to no historical proof to justify its costs.

UniLever’s oft-footnoted Dove brand, for instance, was the first to market to dermatologists. Competing skin cleansers continued their heavy spends in print and on TV. Dove went on to own and leverage the claim of “Most Recommended by Dermatologists” for more than 40 years. The satisfying success of healthcare marketing today is due in large part because of those who, like Dove, are bold enough and care enough to commit to it.

*MM&M*, through its programs, content, and award shows, has consistently demonstrated its commitment to educating and recognizing the talented and passionate people throughout our industry. Well done, *MM&M*, and congratulations on 50 years of making all of us better! — Matt Brown, CEO

Healthcare professionals remain busier than ever, making it challenging to find time to collaborate with colleagues and keep current on the latest information relevant to their field. Social media, tools, and technology have mitigated the pressure created by time constraints, enabling convenient and timely access to vital information and colleagues.

Skipta is the leading social network of specialized online medical communities for verified healthcare professionals. With over 50 vibrant communities and more than 600,000 members, Skipta fosters environments of trust that yield organic peer-to-peer collaboration and provide multichannel outlets for industry to engage, educate, and inspire.

In the many ways that medical professionals rely upon credentialed engagement opportunities and vibrant content from Skipta communities, our industry has valued the many programs, diverse industry content, and events from *MM&M* for 50 years. We salute *MM&M* and congratulate the entire team on 50 fantastic years!