

Parent Empowerment Newsletter

Pharmaceutical Direct-to-Consumer Marketing: When Is It Acceptable?

BY LAURIE KELLEY

After your child is diagnosed with hemophilia, one of the most important decisions you must face as a parent is which product to infuse. Unless your hematologist chooses your initial product for you, you may face a bewildering array of factor concentrate choices, especially if your child has hemophilia A.

Even when your child is older or is transitioning into adulthood, new products keep expanding the offerings. How to choose the best product? How much better is a “new” product, and how do you know if it’s worth a bigger price tag? When you’re new to hemophilia, you may receive product information only from your HTC. But as you become an experienced parent and factor product consumer, you’ll start receiving educational and promotional materials directly from the drug companies – a tactic called “direct-to-consumer” (DTC) advertising or marketing.¹

Advertising is as American as it comes. On its website, the Association of National Advertisers (ANA) writes, “Advertising occupies a special, historic place in American society. Linked to the bedrock principles that shaped our nation – free speech, competition and democracy – it has served the public since colonial times as a source of vital information about our open, market-based economy.”² But in a highly competitive society like ours, advertising can also be misleading, and the government and many watchdog consumer groups routinely patrol advertisements for any hint of inaccuracy.

For this reason, DTC marketing in the pharmaceutical field is controversial. Is it a reliable source of scientific information about products, or just a ploy to influence patients? As a patient or the parent of a child with hemophilia, the best way

to ensure that you’re getting good information – and not marketing hype – is to know what’s being marketed, how it’s being marketed, the scientific facts behind the slick ads, and how to choose the right product for you. This Pharmaceutical Marketing 101 primer will show you how.

Advertising in the Pharmaceutical Industry: An Overview

Open a copy of *Reader’s Digest*, or simply turn on the TV: American consumers are bombarded by advertising from the pharmaceutical industry. “Big Pharma,” the most profitable industry in America, spent \$4.2 billion in 2005 on DTC advertising.³ It also spent about 35% of its revenues on marketing and administration in 2001, an extremely high percentage for any industry.⁴ Most of this money was spent by companies trying to attract patients to use their drugs.

Pharma markets to consumers in many ways, including print ads and TV commercials. It also markets by investing in relationships: sponsoring research by doctors, inviting physicians as members of advisory boards or speakers’ bureaus, giving donations or funding trips, and holding symposia. In 2000, the ten largest pharmaceutical companies spent \$1.9 billion on promotional events alone.⁵ Free product samples also help sway doctors to prescribe a particular medicine. In her book *The Truth About the Drug Companies*, Dr. Marcia Angell reports that in 2001, drug companies spent \$5.5 billion to promote nearly \$11 billion worth of free samples to physicians; and in 2005, pharma spent \$7.2 billion promoting drugs to physicians.⁶

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¹ Although direct-to-consumer marketing refers to any advertising to consumers in any industry, in this article it will refer primarily to the pharmaceutical industry, where it remains highly controversial. ² www.ana.net/advocacy2/content/advamerica ³ US Government Accountability Office report, number GAO-07-54: “Prescription Drugs: Improvements Needed in FDA’s Oversight of Direct-to-Consumer Advertising” (December 14, 2006) estimated that spending on DTC was growing at approximately 20% per year. ⁴ *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*. Marcia Angell, MD. New York: Random House, 2005. ⁵ “Beyond Advertising: The Pharmaceutical Industry’s Hidden Marketing Tactics.” Mary Ebeling. 2/21/2008. Published on Center for Media and Democracy (www.prwatch.org). ⁶ GAO report number GAO-07-54.



Sherrell Portrait Design

When our son Tommy was diagnosed with hemophilia A twenty years ago, we were fortunate to be living in Boston, a medical mecca. Still, we were told there was only one product and one home care company to use. In the years before the Internet and email, I blindly believed that; I was unaware that I had a choice. Maybe that's why I am now such a firm believer in choice, and in going straight to the source to get information about factor – from the manufacturers themselves.

LA Kelley Communications was one of the first companies, if not the first, to promote “direct-to-consumer” contact in the hemophilia community at a time when the community was fiercely attacking the pharmaceutical companies to get compensation for the HIV holocaust. As the mother of a baby with hemophilia, I felt I was not getting all the information I needed about safety in our blood supply. To make decisions about changing products, I needed information beyond what NHF and my HTC provided. Everyone had some kind of bias, and one source of information just wasn't good enough. As a person with a business background, I craved the scientific information the manufacturers had. Luckily, being married to a scientist helped my understanding of products and the blood supply. But I realized that not everyone has a business background or a scientist in the house. So to make sure that as consumers, we get a more complete viewpoint, I decided to promote consumer contact with “pharma” nationally, and balance it with hard-hitting consumer education. I wanted to teach people how to see our community's needs from the viewpoint of empowered consumers. In 1990, my book *Raising a Child With Hemophilia* published the first overview of the hemophilia industry and products from a parent's point of view.

Since 1990, LA Kelley Communications has not waived in its fundamental belief that bleeding-disorders consumers are smart, are capable of understanding this business and the products, and should have direct contact with all players: advocates, other families and patients, payers, home care companies, HTCs, and the drug companies. We offer direct-to-consumer promotions, which help support our humanitarian work in developing countries. And we balance this with our free educational resources that carry distinct messages: Read. Learn. Ask questions. And above all, think for yourself. While we value free speech even in advertising, perhaps we value independence and choice as much or even more. ☺

inbox

I JUST WANTED TO LET YOU KNOW HOW MUCH I ENJOYED AND appreciated your recent article on tattoos. This is an issue my son has been dealing with for a couple of years. This is an important concern for tweens and teens, and their parents. Getting a tattoo is just another way of seeing themselves as “normal” and being able to do what their friends are doing. Thank you for sharing.

✉ Bert Brown
Indiana

✉ Brian J. Ward
Chairman of the Board
HBDA

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PEN is a newsletter for families affected by bleeding disorders that is produced and edited by a parent of a child with hemophilia. It is a forum that promotes an active exchange of information and support among divergent groups in the national and international hemophilia community.

PEN does not accept advertising and uses brand product names and company names pertaining only to news and education.

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THANK YOU FOR MENTIONING THE BLUE CROSS ISSUE IN Alabama in your February newsletter. I am excited to update you on our progress with BCBS. They intended to enter into a sole provider contract with a large national provider, but the contract was not executed before we engaged with them. BCBS has revisited the issue and decided to create guidelines that a provider will need to meet. Hemophilia and Bleeding Disorders of Alabama, Inc. (HBDA) has been given the opportunity to review the guidelines prior to implementation and voice any opinions or objections that we might have. Also, BCBS has hinted that they like the New Jersey standards of care (I gave them a copy of the legislation) and might be willing to help us lobby it through the Alabama legislature. I will keep you updated as information becomes available.

BY SUE COWELL



Chapter Funding and Industry Involvement: *Finding the Right Balance*

As the relatively new executive director of Hemophilia of North Carolina, I ponder daily the amount of contact there should be between our members (consumers) and industry – the home healthcare and pharmaceutical companies. It's a fine line that those of us involved in chapters know very well. Our board of directors can tell you that I have lost more than one night's sleep agonizing over who to include in our events and programs: Is the person who has a bleeding disorder and works for a company a *member* – or an *industry rep*? Should we even solicit funding from corporate sponsors?

I've spoken with other chapter representatives who face the same challenge, and the opinions are as varied as flavors

of ice cream! Some have no interaction with industry, while others welcome industry reps in all areas of the chapter. My observations are that the majority fall somewhere in the middle, as do we.

What guides me (and lets me sleep a little better at night) is staying focused on our mission of providing our members with the education they need to make the right product and provider choices for themselves and their families. Over the past year our chapter has provided quality programs and services to our members. What's most impressive is watching new people network, learn more about how to face the challenges that arise and, best of all, stay connected. Our quarterly newsletter also lets members know about what's happening with the chapter, and offers resource information and the latest articles on a wide array of topics. Without the support of industry in sponsoring the programs and purchasing advertising space in our newsletter, many of these opportunities would not be available.

In my opinion, the key to straddling that fence – balancing information and marketing – lies in the ability of the chapter to provide services with proper disclosure, to make sure that members have a clear understanding of what is being offered, and most of all, to ensure that members take the time to discuss treatment options with their HTC before making any product or provider changes. Are we able to accomplish this

100% of the time? Definitely not. I've heard stories of consumers asking to switch products because they like the rep better at the other company, and I've witnessed business cards being passed to consumers ever-so-discreetly at a non-marketing event. However, overall I find that there is a good, respectful relationship between the members and industry, with some valuable opportunities to continue to provide education.

As consumers, our lives are filled with information from the Internet, television, radio and newspapers. Every day we watch commercials about products or see banners scrolling across the computer screen on the latest new and improved goods or services to make our lives better. Information is at our fingertips and coming at us from all directions. Being an educated consumer means being able to filter information, do more research, and know your choices. As a community, it's more important than ever that we become educated healthcare consumers to keep pace with rapid changes in products, services and insurance benefits. We all need to be armed with the proper information and be active participants in managing our healthcare. The chapter's role as "information broker" is to make the process a little less bewildering, and to provide the right tools for wading through the information, in a way that doesn't erode our members' confidence in our ability to follow strict ethical guidelines and protect their personal information. ☺

Sue Cowell is executive director of Hemophilia of North Carolina. Previously, she worked in the casino industry in New Jersey for more than 25 years, and volunteered with the United Way and with local youth sports teams as president, volunteer coordinator and coach. She lives in Morrisville, North Carolina, with her husband and two teenage daughters and can be reached at info@hemophilia-nc.org.

LA Kelley Communications, Inc.





BY PAUL CLEMENT

Choosing a Factor Product: *Who To Believe?*



Inhibitor Insights is a PEN column sponsored by Novo Nordisk, Inc.

When you have an inhibitor, nothing is more important than choosing a product to help stop bleeds, or to use in immune tolerance induction (ITI). But where do you get your information? Do you carefully read product brochures or journal articles? Do you leave the decision up to your physician? Do you take the advice of a pharmaceutical or home care representative, or another parent or patient? Who do you believe?

No matter where you get your information, you have many things to consider when choosing a factor product. First, of course the product must be efficacious – good at stopping bleeds. And it will be either plasma-derived or recombinant. But ask more questions: Does it have the potential to transmit viruses or other pathogens? What type of viral inactivation process, if any, is used in manufacturing? What about purity, cost, diluent volume, assay size and half-life? What's the risk of developing inhibitors or allergic reactions when using the product? Is it easy to transport and store? Is there a risk of significant side effects? Are infusion needles or needleless reconstitution devices included? Does the manufacturer provide insurance gap protection or an electronic logbook?

With so much to consider, it's best to prioritize. Efficacy is of prime importance: the factor product must work effectively to stop bleeding. But the weight given to other considerations is often unique to each patient. For example, people with low-titer, low-responding inhibitors, and those on ITI, might place high importance on the availability of large assays. Parents with a newly diagnosed child who doesn't have inhibitors may rate

large assays lower in priority. Families with a young child with hemophilia, especially one undergoing ITI, might be attracted to a needleless reconstitution device, while an adult might consider this an inconvenience. Cost may matter little to people who work for a large company with exceptional insurance benefits. For those with inhibitors who work for small companies, are uninsured, or have a low lifetime cap, cost is paramount. You can burn through a lifetime cap within a few years. Of course, if you have a high-titer, high-responding inhibitor to factor VIII, your choices may be limited to two bypassing products: FEIBA VH and NovoSeven®.

Many families feel overwhelmed by all the options, and believe that product decision should be left to healthcare professionals.¹ And indeed, for the families of newly diagnosed children seen at an HTC, leaving the decision up to your physician is usually a wise choice. But increasingly, your physician's hands may be tied. In an effort to contain costs, large insurance companies and health maintenance organizations increasingly restrict their formularies, which in turn may restrict your physician's ability to be objective when choosing a factor product or bypassing agent.

An alternative approach is to read product brochures from the pharmaceutical companies, and meet with local pharmaceutical reps. Many of these reps serve on the board of directors of local hemophilia foundations. They staff committees, volunteer at hemophilia summer camps, and distribute information about their products at local foundation information days or annual meetings. For years, hemophilia was unique among chronic

disorders in that pharmaceutical reps had direct contact with patients, so they could market their products directly to the consumers – who might then request a script for the product from their doctor.

Are educational materials from pharmaceutical companies a source of unbiased information? As an educated consumer, keep in mind that the goal of any pharmaceutical company is to convince you that a particular drug is better than the others. In pharma literature, the positive points of the product may be magnified, while the negative aspects may be downplayed. For example, a company selling a plasma-derived product may downplay its potential to transmit blood-borne pathogens, while highlighting its low cost. The same company, when selling a recombinant product, may highlight the fact that the product contains no plasma proteins, yet downplay the product's high cost.

Unfortunately, some consumers don't even know the name of the product they use. Some don't know the difference between the product Recombinate and the term *recombinant*. And most consumers don't know what type of viral inactivation process is used in manufacturing their factor.² This makes it hard for many people to read a pharma brochure critically.

The best approach combines (1) becoming a partner with your physician to determine the product that best suits your needs, and (2) reading pharmaceutical materials. Educate yourself. Read product brochures. Attend conferences, and read hemophilia newsletters and magazines. Talk to others and talk to your physician. When you understand your choices, you'll make a well-informed decision. ☺

^{1,2} Edna P. Bolivar, Rinah I. Shopnick, Pier M. Mannucci, Alessandro Gringeri, Doreen B. Brettler, 1995. "The knowledge and perception of factor concentrate in persons with haemophilia A." *Hemophilia* 1(4), 232–235 doi:10.1111/j.1365-2516.1995.tb00081.x

BY ZIVA MANN



The Littlest Market

It's bedtime, and I offer Akiva a toothbrush, temptingly spread with toothpaste. "No!" he yells, grinning at me. "Nonononononononono!" We stare at each other, and he explains. "I don't want the toofbush, Mummy." Oh.

"Okay," I say slowly, "then maybe I'll use it." I look at the toothbrush as if it's really special. Akiva watches me closely. "Hmmm," I say. "I wonder what the toothpaste tastes like? I bet it's grape. That's my favorite." Akiva is now thinking hard, trying to decide if he likes grape, too. I open my mouth wide, as if I'm about to use the brush, and Akiva cracks. "No! I want it! Is my toofbush!"

It's not hard to persuade a two-year-old to do what you want. Lay your bait just right, and you can persuade him that what you value is what he should value, and that he wants – no, he needs – the object being dangled before him. I've used more sophisticated versions of this trick on Akiva's elder brother Shai, showing him how the bigger guys get their factor in their veins, or even self-infuse. It's salesmanship, a kind of marketing of my values to my kids, and it's absurdly easy. But I worry that if I'm good at it, the professionals are better. Much better. And whose values are they selling? Or are they just selling stuff?

Blue's Clues characters are on Akiva's diapers. Our pediatrician hands out Cheerios counting books. Disney rules over my kids' toothbrushes. And Spiderman and the "Cars" movie are fighting over Shai's underwear drawer. I'm not sure there's anything wrong with all these images, but when I see my boys learning the lesson plans that some advertiser wrote for them (Blues Clues = fun!), I start to wonder.

When we go to the grocery store, Akiva wants the Blue's Clues diapers and Shai wants the latest superhero thingamajig. These characters have a grip on my kids' loyalties: I know this picture, they think, and it's cool/fun/silly/good, so I should tell my mom to get it. Yeesh. Call me a cynic, but I'm

tired of trying to persuade a shopping cart full of boys that we're not buying the super-cool hero lunchbox instead of the plain (and cheaper) one. It bugs me that advertisers use my kids to pressure me into making choices without evaluating what we really need. Financially and psychologically it's just a bad, bad idea for me to try to buy happiness – or to model the attempt for my boys. (Blues Clues = fun, right?) But when they're hollering in the aisles, it's awfully tempting to give in.

In a perfect world, my kids would learn to buy the things they need. They'd learn to ignore the advertising guru whispering in their ears, *This will make you cooler, stronger, tougher, happier... buy it now!* They'd be smart about budgets, making carefully balanced choices between need, desire and resources. And they'd bring the grandchildren to visit. Lots of grandchildren. In a perfect world, that's how it would go.

But reality is full of whispered advertising voices, and one of them is on Akiva's bum right now. If my kids can't yet tell the difference between reality and a TV cartoon, then how can they differentiate between value and salesmanship? Diapers with Blue's Clues don't absorb more. They're not the best bargain. They're just cute. And they signal a pattern of reflexive, thoughtless consumerism that worries me. So one of the values I intend to imprint on the boys is the cynicism my mother gave me. "Why do you want that?" she'd ask. "Do you *need* it?"

I hope that my kids, growing up in a world saturated with advertising, will ask those questions. And not just when they choose toothbrushes and diapers, but when they choose healthcare. "Why is that brand of factor better?" I hope they'll ask. "Or that doctor or home care company? Why do I want that particular provider or brand? Do they have what I need? Do they offer better value?" And while they're at it, "When are we going to take the kids to visit their grandma?"

Children are perceived as a market. In 2000, children aged 12 and under influenced household spending of over \$600 billion (McNeal, 2001, stat qtd. from www.mediafamily.org/facts/facts_childadv.shtml). Yet the American Academy of Pediatrics (APA) has suggested avoiding advertising to children, "particularly children ages eight and younger who lack the cognitive ability to recognize advertising's persuasive intent" (www.apa.org/monitor/jun04/protecting.html). And approximately 80% of advertising targeting children falls into four categories: toys, cereals, candies, and fast-food restaurants (Kunkel & Gantz, 1992, qtd. in "Report of the APA Task Force on Advertising and Children," 2004). The APA notes that teens are especially vulnerable to advertising; for more on this, visit www.apa.org/monitor/jun04/driving.html. It's interesting to note that advertising in the hemophilia community increasingly targets teens and young adults.



Five Questions for WellPoint

The latest shakeup in the ever-evolving hemophilia industry has been the creation of in-house specialty pharmacies by insurance companies. In some cases, this change involves the forced switching of home care provider. In "The Wicked Switch of the West" (*PEN*, Feb 2008) we described how patients perceived switches by WellPoint, one of the nation's largest healthcare insurers, to PrecisionRx, its in-house provider. With many advocates and rival home care companies crying foul, *PEN* asked Bob Charles, staff vice president, WellPoint Specialty Pharmacy, to explain WellPoint's position in the community and its impact on patients and healthcare costs.

1. Please describe WellPoint's current changes/latest trends in hemophilia reimbursement.

Because the needs of our members are squarely at the forefront, WellPoint is committed to a reimbursement model that addresses the total cost of hemophilia care, to make healthcare affordable and durable. As an insurer, WellPoint is uniquely qualified to quantify and manage all related expenditures, across both the pharmacy and medical benefits.

Therefore, the strategy for hemophilia reimbursement is to help control all relevant costs, while maintaining or helping to improve the quality of care our members receive. Beginning with the per-unit price paid for factor, WellPoint will expect reimbursements to match the general acquisition cost in

the community. Undue markups are not acceptable for us or our members.

Additionally, all providers in the hemophilia network will be required to manage assays, and dispense product within a much smaller range than the industry standard.

Finally, all providers in the hemophilia network will be asked to manage compliance to the shipped product, with outbound calls to the members scheduled on a risk-assessed basis.

2. Does WellPoint view the hemophilia community differently than it views other chronic disorders in terms of care, costs, needs, or advocacy?

From a general standpoint, WellPoint strives to provide all members with chronic diseases a similar care management model. Multi-disciplinary teams (physicians, pharmacists, ethicists, nurses, case managers, and technical personnel) work in tandem to develop evidence-based treatment algorithms. These algorithms are updated frequently as clinical evidence evolves.

Hemophilia management also follows this model, and WellPoint allocates significant resources to help prevent disease progression and avoid downstream costs. To attain this goal, WellPoint follows MASAC (Medical and Scientific Advisory Council) guidelines to ensure that optimal outcomes are achieved.

When outcomes are optimized, the needs of the hemophilia community are

addressed. If a member is compliant, they have fewer unabated bleeding episodes. With fewer unabated bleeding episodes, target joints are preserved. If joint integrity is preserved, replacement surgery is avoided. If surgery can be avoided, a member's lifetime caps are prolonged.

From this perspective, WellPoint can in many ways be viewed as a substantial advocate for the member with hemophilia, striving to prolong lifetime benefits, prevent disease progression, manage co-morbidities, and help improve quality of life.

3. Why did WellPoint create its own in-house specialty pharmacy?

Therapeutic consistency and alignment of incentives are the main reasons that WellPoint integrated specialty pharmacy. An integrated pharmacy is best suited to implement WellPoint's clinical guidelines, and avoid therapeutic variations, while providing services in a manner that helps to control the costs of care.

Assay management is a perfect example. A prescription can be dispensed at the industry standard rate of +/- 10%. WellPoint has set a much more stringent target for assays, and will expect all other pharmacies in the hemophilia network to do the same.

Lastly, WellPoint can also obtain better acquisition costs due to the number of members we have nationwide. These prices are passed on to the member in the form of lowered cost shares and extended lifetime caps. Conversely, an

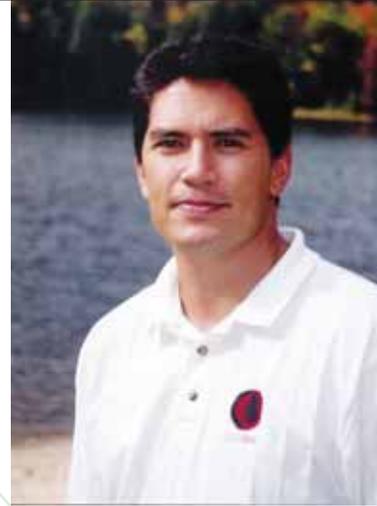
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Transitions is a PEN column sponsored by Baxter BioScience

BY KEVIN CORREA

PEN welcomes Kevin Correa, our new *Transitions* columnist. Kevin lives in Georgetown, Massachusetts, with his wife Patty and three young children. Kevin earned a degree in social anthropology from Harvard University. "With no personal ties to hemophilia," says Kevin, "I hope to bring a fresh perspective to *Transitions*." Kevin is particularly interested in the relationship between culture and public health. His debut novel *The Kokopelli Theory* is a medical thriller about the origins of hepatitis C.



Unfortunately, Fishing Isn't Exercise

Given the importance the medical community places on exercise in the management of hemophilia, I found it staggering that 60% of 13- to 21-year-olds manage their hemophilia by avoiding physical activity.¹ Could it be that you teens actually *listened* to the words of caution you heard growing up? Whatever the reason, as a young man starting to take control of your life, you need to begin making health management decisions of your own. One of your first should be a commitment to become physically fit.

Mixed Messages

There's a disconnect between the recommendations of the medical community and practice in the home. The National Hemophilia Foundation's list of "safe and recommended" sports may inadvertently contribute to this. Naturally, NHF emphasizes low-impact activities that won't stress joints: sports like frisbee, sailing, archery, and fishing.² As an avid angler, I can tell you that when comparing fishing to, say, sleeping on a couch, you're splitting hairs in terms of exercise value. The problem with the NHF list is that many of the sports are more recreation than exercise. The lack of meaningful exercise within the community is apparent, as the incidence of childhood obesity among hemophilic children is twice that of the general population.³

By the time you were in your early teens, you were probably used to engaging in low-risk activities providing little or no exercise value. This sedentary lifestyle often results in weight gain, placing added stress on already compromised joints. But inactivity – with or without hemophilia – puts any teen at risk for ailments like heart disease and diabetes.

Better Late...

If you don't have much experience with exercise, starting from square one can seem daunting. I'm not saying you should try out for the college football team. But consider giving an intramural sport like soccer a shot. Or if you're working, play on your company's softball team. If intramurals and company teams aren't your cup of tea, it's time to hit the gym.

Remember: Any exercise you do should include both *aerobic* and *resistance* training.

NHF hit the nail squarely on the head by listing swimming as

a "safe and recommended" activity. Swimming is the gold standard for aerobic exercise when it comes to hemophilia because of the extremely low impact on the body. That said, if water isn't your thing, stationary bikes are a good aerobic substitute.

On the other side of the equation is resistance training. Its goal is to increase strength and flexibility, promoting greater joint stability. Growing evidence suggests that this increased stability results in the reduced frequency and severity of bleeds. And some studies have found that exercise even increases circulating levels of factor VIII in people with mild to moderate hemophilia.⁴

We're all aware of the physiological benefits of exercise. But there's also plenty of evidence demonstrating its value in increasing psychological, social and emotional wellbeing. And while the threat of bleeds will always exist, if you perform exercise correctly and with adequate supervision, the benefits often outweigh the risks.⁵

Teaching By Example

Jeff Kallberg's experience shows that it's never too late to start exercising. Now 40, Jeff recalls that by his early teens he began developing arthritis and had difficulty getting around.

In his early twenties, Jeff asked his orthopedist to recommend a physical therapist. The doctor warned against exercise and weightlifting because it would "wear his joints out." But Jeff persisted until the doctor agreed to send him to physical therapy.

"Those six sessions of physical therapy changed my life," says Jeff. "I learned the basics for a healthy life. I began to eat right and exercise." Over the next few years, Jeff's mobility increased dramatically, and he experienced a marked decrease in frequency of bleeds.

Today Jeff is a physical therapist helping patients – many with hemophilia – lead healthier lives. He promotes regular, structured exercise and advises patients to join a class that forces them to exercise on a fixed schedule. "I see people on prophylaxis today and think, 'You just infused. Don't go sit on the couch and play video games. Put that factor to work!'"

Jeff's strong views on the role of exercise carry over into a social context. "As a group, we're expensive patients," he says.

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¹ Nazzaro, A. Owens, S.; Hoots, W.; Larson, K. 2006. *Am J Public Health* 96(9):1618-1622. ² National Hemophilia Foundation website. ³ Phillips, J. 2006. *Bloodlines* 1:3. ⁴ There have been no large-scale studies on the effects of exercise on bleed frequency and severity, nor of increases in factor VIII, but numerous small studies have found these results and suggest further inquiry. ⁵ Coelho, J.; Cameron, K. 1999. *Strength and Conditioning Journal* 21(5):30-33.

BY RICHARD J. ATWOOD

The Most Famous Celebrity with Hemophilia

RICHARD BURTON: A LIFE

Melvyn Bragg, 1988. Warner Books.

ELIZABETH

Randy Taraborrelli, 2006. Warner Books.

The lives of Elizabeth Taylor and Richard Burton intersected with volatile chemistry, and a small part of that mixture involved hemophilia. Yet the role of hemophilia in their celebrity relationship is difficult to uncover, and was possibly meant to remain hidden behind their public presence.

Elizabeth Rosemond Taylor was born in 1932 in London, England, and Richard Burton (Richard Walker Jenkins) in 1925 in Pontrhydyfen, Wales. They both began acting careers, and their personal relationship developed while filming the movie *Cleopatra* in 1962; the love affair between Antony and Cleopatra seemed to transpose into the torrid affair and the two stormy, highly public marriages of Richard and Elizabeth.

In *Elizabeth*, we learn that in May 1964, Richard was upset after being booed as the lead in *Hamlet* on Broadway. He began drinking heavily and then argued with Elizabeth, who was watching a Peter Sellers movie on television. During their argument, Richard kicked the television screen with his bare foot and cut a toe to the bone. The blood flow wouldn't stop for an hour. At the hospital, Richard received a dozen stitches. There, Elizabeth discovered that Richard suffered from mild hemophilia, a condition he had known about since childhood, as four of the Jenkins brothers had "the disease of kings."

Richard Burton and Elizabeth Taylor In *Cleopatra*

As a precaution, Richard began using an electric razor to avoid nicks while shaving, and Elizabeth ensured that a supply of vitamin K was available for his hemophilia. When Elizabeth learned that there were "more than a hundred thousand sufferers in the United States alone,"¹ she and

Richard contacted the National Hemophilia Foundation for ways to raise funds for public awareness. In June 1964 the couple established the Richard Burton Haemophilia Fund, with Elizabeth as chair. For raising hundreds of thousands of dollars, the fund was recognized in the June 17, 1964, issue of the United States House of Representatives Congressional Record, and in the June 27, 1964, issue of the *British Medical Journal*.

Richard Burton: A Life is an in-depth biography, and yet hemophilia is mentioned only once and

the Richard Burton Haemophilia Fund isn't mentioned at all. *Elizabeth* contains a short section titled "Richard's Hemophilia." The index includes two listings for hemophilia, under "Charities and Causes" and under Richard Burton; but there is no listing for the Richard Burton Haemophilia Fund, although NHF is listed.

Richard Burton had more pressing medical problems than his hemophilia. Drinking and smoking harmed his liver and lungs, and he also suffered from epilepsy and acne. He blamed his arthritis on neck and back injuries from playing rugby as a youth, and on the "weak Jenkins bones." Richard's hemophilia didn't prevent him from fighting, and was only mentioned in *A Life* because of the 1964 bleeding incident. For some reason, perhaps a fear of being stigmatized, the role of hemophilia in Richard Burton's life never reached center stage. 🌀

¹ *Elizabeth*, p. 302. Taylor was incorrect; there were only about 20,000 with hemophilia in the US.

Transitions... continued from page 7

"We have an obligation to do whatever we can to become responsible consumers within the healthcare system. That means living healthier lives by eating right and exercising. I'm not saying you have to be a star athlete, but you should do whatever you can to help manage the costs of your health."

The Ball Is in Your Court

When you were young, your parents were responsible for your wellbeing. It may have been their best judgment to avoid cer-

tain sports or vigorous exercise. But as you take greater control over managing your health, you owe it to yourself to reevaluate those early decisions. The science points to a healthier life through exercise. So if you can exercise, you *should!*

Discuss exercise options with your doctor or physical therapist today. Frisbee and fishing are fun, but they won't put you on the road to a healthier life. As Jeff puts it, "Your body is probably capable of a lot more than you think." 🌀

But one of the newest and most controversial selling tactics is pharmaceutical DTC marketing. From 1996 to 2004, DTC expenditures rose more than 500%.⁷ DTC bypasses the traditional method of educating doctors about new drugs so they can inform patients. DTC goes straight to consumers with colorful ads. Pharma claims these ads are beneficial because they encourage patients to ask their doctors about specific drugs. But while advertising is expected in a capitalist society like ours, the average consumer is not well educated about drugs or their side effects. The unfortunate result? Consumers may be easily misled by advertising.

Pharmaceutical DTC marketing is legal only in the US and New Zealand. No other developed country permits it. But along with this great liberty to advertise come some strict rules. Government agencies, watchdog groups, and even physicians monitor how companies market their drugs. In the US, drug companies are required by law to send their DTC ads to the FDA when they launch a new ad campaign; and the FDA must ensure that the ads fairly represent the risks and benefits of using a particular drug. Companies that defy the rules about DTC can be heavily fined, and their product may be pulled from the market.

Much DTC marketing occurs in the traditional pharmaceutical field – pills. Nexium®, Lipitor® and Viagra® are heavily marketed, for example. But the biologics industry,⁸ which includes factor, has also adopted DTC advertising. Traditionally, factor manufacturers have focused on the prescribing doctor as a target audience for their marketing, but a new kind of hemophilia patient arose from the ashes of the HIV holocaust of the 1980s – a consumer who was wary of both physician and pharmaceutical company, who asked more questions, and who demanded direct answers. As hemophilia patients become more independent of their HTCs and more educated about their disorder, and as the Internet revolutionizes mass communication, the seven current factor manufacturers⁹ are responding to more direct patient requests. They're also reaching out to attempt to directly influence patients' choice of product.

One of the drug manufacturers' main DTC tactics is to show that products within a single class are not the same, and many hematologists also hold this position. The key to successful marketing in any field is *differentiation*: the idea that there's something unique in a product, something the competition can't or doesn't offer. How do competing factor manufacturers differentiate products that seem the same? How do you distinguish Kogenate® FS from Helixate® FS from ReFacto®, Advate from Xyntha™, Monoclate-P® from Recombinate? Marketers do this by *branding*.

Branding: The Key to Differentiation

If differentiation is key to marketing, then the brand embodies that difference. Branding is essential in DTC advertising. A brand is a name, term, design, symbol, or other feature that differentiates a product or service from its competitors. Brands

make a product or service unique – at least in the minds of consumers, if not in fact.

The term “brand” comes from ranching: distinctive marks seared onto the flanks of cattle with a hot iron.¹⁰ Each mark is registered with a particular ranch to denote ownership. Why? Most cows look the same, and a brand differentiates one from another. When a steer strays from the herd, its brand identifies its owner.

In marketing, brand is all about image, meaning and connotation – not necessarily about facts. What does the brand Harley-Davidson bring to mind? Probably not transportation, or even motorcycles. “It’s about an attitude of full-blown freedom, unleashing the rebel inside, and living your wild side,” says marketing expert Karen Post. “Successful brands connect through values, not product features.”¹¹

Companies spend millions of dollars building a brand, long before the product even reaches the market. An effective brand elicits positive feelings and loyalty to the products and services of a company, and to the company itself. Marketing guru and best-selling author Alan Weis explains, “Branding is about passion, emotion, and visceral impulse, not about hard, cold facts.” He adds that the end result of branding must be a purchase. Emotion, not logic, makes people buy. This is true whether the seller is a manufacturer of cars, computers, cosmetics – or pharmaceuticals.

The Hemophilia Market

Advertising is common in a free and open marketplace, but the US hemophilia community isn't a typical market. The hemophilia market is an *oligopoly*, where just a few manufacturers create a limited number of products for a tiny market of about 17,500 consumers. Break it down even further by subset or *segment*, and the market becomes smaller and more defined. Baxter and Novo Nordisk wrestle for the attention of only 1,200 inhibitor patients. CSL Behring, Baxter and Grifols duke it out for the brand loyalty of only 5,000 people with hemophilia B. And CSL Behring dominates the von Willebrand Disease segment.

Hemophilia A patients represent the biggest market segment in number of patients. Consequently, they have the widest selection of products to choose from. Most marketing has been and remains targeted to these patients.

Advertising in the hemophilia market is much different – and more controversial – than advertising in an open consumer market. We are consumers who don't have the option *not* to buy. Because we must have factor, we are a *captive market*. We're also a small market, not subject to the supply-and-demand rules that affect most free markets. And we consume biologics, life-saving drugs for a chronic disorder. In short, without constant scrutiny by government regulatory agencies and by our own advocate-watchdogs, we're a market that can easily be abused. Maybe because of this, and because of the devastation wrought by HIV, our market is also unique

⁷ Big Bucks, Big Pharma: Marketing Disease and Pushing Drugs. Medica Educations Foundation. DVD only, www.mediaed.org. ⁸ Biological drugs are made from a living organism or its products. ⁹ Bayer HealthCare, Baxter BioScience, CSL Behring, Grifols, Novo Nordisk Inc., Talecris, Wyeth. ¹⁰ “Brand” is also related to the Old English *baerman*, to burn. “Brand-new” goes back to the Middle Ages, referring to pottery or metalwork that has just been pulled from the fire where it was hardened. ¹¹ “Brands Are about Relationships, Not Transactions.” Karen Post. www.brandingdiva.com.

in its passion for education, information and action.

"[A smaller marketplace] creates a stronger connection in the community," notes Klaus Davidsen, director of NovoSeven® marketing. "Patients tend to get more involved." Kim Tully, product manager for Helixate FS, agrees. "Consumers play a much more active role in their treatment and in making key decisions about treatment." And Baxter's senior director of marketing, Michelle Priefer, says, "From our research, about 50% of patients are involved in their own decision making. In other therapeutic areas, it's only 5% to 20% of the time. That's a big difference."

"Hemophilia patients tend to be highly organized and well connected, well read, and more savvy than the typical consumer," notes Marianne Drysdale, senior director at Bayer HealthCare. "Because this is a chronic, lifetime bleeding disorder, they are in this for the long haul. We believe consumers are looking for a long-term relationship that extends well beyond the product or service itself."

The desire to make our own treatment decisions makes us a natural target for pharma DTC marketing. Yet some hemophilia patients still don't know which product they are using, aren't sure why their doctor recommended switching products, aren't sure what to do when a new product like Wyeth's Xyntha¹² – just approved in March 2008 – becomes available, and have trouble separating brand message from scientific fact from clinical implications.

These patients may be most susceptible to marketing tactics that encourage them to blindly switch brands. They risk switching to products that may cause problems for them because of insurance caps, home care provider access, or potential side effects. These patients need first to understand the different products available, and second, to learn how pharmaceutical companies brand these products to make them more appealing to hemophilia consumers. Factor consumers need to recognize when a DTC ad appeals to their emotion, not to their reasoning.

Differentiation in Factor

For such a small market, we have a lot of products to choose from. For hemophilia A patients, there are plasma-derived products: Alphanate®, Koate®-DVI, Hemofil M and Monoclate-P. And there are recombinant products: Advate, Recombinate, ReFacto, Helixate FS, Kogenate FS, and now Xyntha. Inhibitor

¹² Wyeth was not available to be interviewed for this article.

¹³ Kogenate was the exact same drug as Helixate; Kogenate FS is the exact same drug as Helixate FS.

patients can try FEIBA VH (plasma-derived) or NovoSeven (recombinant). Hemophilia B patients can select plasma-derived products such as Mononine® or Alphanine®, or the recombinant BeneFix® (see table below).

Most patients know right away whether they want a plasma-derived or recombinant product. Some patients, like certain inhibitor patients, have no choice: sometimes only one product is effective in stopping bleeds. Inhibitor patients and hemophilia B patients who want only a recombinant product also have no choice: NovoSeven is the only recombinant factor VIIa, and BeneFix is the only recombinant factor IX product. The recombinant hemophilia A market has the greatest need for product differentiation, since 85% of hemophilia patients are factor VIII deficient, and most of them want recombinant products.

Product differentiation occurred naturally with the development of recombinants: Recombinate was the first recombinant factor VIII product, introduced in 1992 and now called *first-generation*. Recombinate had no direct competitors, as it was not derived from blood. Eventually more recombinant factor VIII products entered the market: ReFacto, Kogenate, Helixate and Bioclate®.¹³ Then came the first *second-generation* product: Kogenate FS, made without animal products in the final formulation. This helped differentiate products even more. In 2002 came a *third-generation* product, Advate, using no animal or human proteins in any phase of its manufacturing. Since Advate was the only product of its kind, it occupied a special niche and was instantly differentiated.

The newest product, Xyntha, is also a third-generation recombinant factor VIII product, set to market directly against Advate. With this plethora of products, how can patients choose the right one for them?

US Hemophilia Products

Competition — and heavy advertising — is intense with factor VIII products

	Recombinant			Plasma-derived		
	Factor VIII	Factor IX	Other*	Factor VIII	Factor IX	Other*
Baxter	Advate Recombinate			Hemofil M Monarc-M™	Bebulin VH	FEIBA VH
Bayer	Kogenate®FS					
CSL Behring	Helixate®FS			Monoclate- P®	Mononine®	
Grifols				Alphanate®	AlphaNine® SD	
Novo Nordisk			NovoSeven®			
Talecris				Koate®-DVI		
Wyeth®	ReFacto® Xyntha™	BeneFix®				

Note: Recombinate is a first-generation product. Kogenate FS, Helixate FS, and ReFacto are second-generation products. Advate, BeneFix and Xyntha are third-generation products.
*Inhibitor bypassing products

Despite differences in all these products' sources and manufacturing, they have commonalities: All are considered safe by the FDA, even the plasma-derived. All are efficacious. So how they are differentiated? In the way they are branded, packaged and sold to the community.

Branding Factor: Intrinsic Attributes

Attendees at the latest National Hemophilia Foundation (NHF) annual meeting found out just what DTC marketing means. Entering their hotel rooms every night, they pushed aside a stack of marketing literature and ads stuffed under their doors by factor manufacturers. For consumers not attending NHF meetings, ads may arrive by mail, from HTC's or home care companies, at local chapter events or in chapter newsletters. Most notoriously, ads also appear throughout and on the cover of *HemAware*, NHF's magazine. Even the for-profit home care companies now feature pharmaceutical ads in their newsletters and magazines.

To differentiate, a product must capture some unique selling position and promote it with color, shape, tagline and logo to generate an emotional appeal to the end user – you. Differentiation can focus on *intrinsic* attributes inherent in the product, or on *extrinsic* attributes in the form of features and benefits that come with it.

When Advate was introduced in June 2004, it had a distinct intrinsic differentiation: it was the first third-generation recombinant factor VIII product, using no animal or human proteins or products in its manufacturing. Baxter put a huge effort into marketing Advate as theoretically safer than all other factor VIII products. Its ads compare one clear marble (representing no blood products) to marbles with a flash of red in them (representing products using added human or animal proteins). Advate's slogan is "The clear choice." Still, Advate only recently became the number-one brand.

Advate's slower than expected "uptake" may have had two main causes. First, consumers often feel that a first product is the original, the best. Recombinate, the first recombinant factor concentrate, clung to its title as the most prescribed brand, despite a competing product, from the *same* company, with no human or animal proteins. "Better products don't win," claims Jack Trout, best-selling branding author. "Better *perceptions* tend to be the winners." And Michelle Priefer notes, "Certain patient segments may rush to try new things; others need greater reassurance on safety and efficacy. Even the Recombinate uptake was slow at first, because people wanted to wait and see. Once these were assured, then people switched." Consumers also didn't perceive a greater value in Advate that justified its higher price tag.

Second, most hemophilia patients are "brand loyal." Once they use a product, they're reluctant to switch, even when a technologically more advanced product enters the market. Recombinate was perceived as a winner. It worked, it had a track record – why switch? Yet for some patients, this reliance on intrinsic attributes isn't enough; many look to extrinsic attributes when making product decisions.

Branding Factor: Extrinsic Attributes

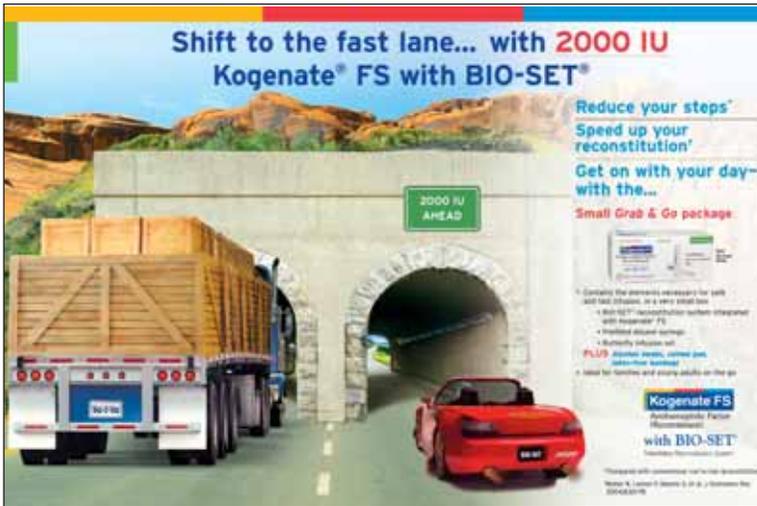
What made Kogenate FS the second-best-selling recombinant factor concentrate for several years? How did it sustain and even expand its market share against Recombinate and Advate?

"One product differentiation...[was] the low diluent volume offered with Kogenate FS," says Marianne Drysdale. Recombinate's large volume was a hindrance for many families with babies and young children, and for teens learning to self-infuse. Bayer captured market share when it introduced Kogenate FS, a drastically reduced-volume factor, with the word "convenience" in its ads. *Attribute ownership* – a product feature that a company can capitalize on – is one of the best ways to differentiate a product or service.

How do Bayer and CSL Behring distinguish Kogenate FS from Helixate FS when these two products are identical? Through extrinsic attributes. Kim Tully points out that Helixate FS comes with Mix2Vial and offers the HelitraxSM System. Yet all factor manufacturers now offer some sort of needleless reconstitution system, like Bio-Set and BaxJect, and some kind of tracking system to record assay and lot numbers, like Advoy and EZ Log. Larger assay sizes became crucial as a burgeoning market segment – the post-1986 crowd – matured and went off to work or college. Everyone wanted these larger assays, but in smaller bottles to fit an active lifestyle. Most of these needs have been met by all the manufacturers.

Extrinsic attributes can also include what a company stands for. To differentiate itself, CSL Behring identifies its products with the attribute of physical activity. Its logo for Helixate FS is a pair of delightfully dirty children's sneakers, and the tagline "Boy will be boysTM." The company sponsors Gettin' in the GameSM events featuring high-profile athletes who have bleeding disorders. Bayer wants to be associated with convenience, so it promotes its smaller diluent size, and its "Grab-n-go" packaging. Its colorful ads feature a red car zipping down the highway, next to a bulky oversized truck – both headed for a narrow tunnel. The tagline? "Shift to the fast lane." Baxter seems to stand for choice, as it offers the widest array of hemophilia products, with the greatest assay ranges. Baxter's "There when you need usSM" campaign features a lighthouse logo, reinforcing this attribute with a wide range of consumer programs.

Celebrities help promote products. Bayer abandoned its little dinosaur mascot Kogee, and now through a program called Team Hemophilia, it helps raise money for NHF by advertising at NASCAR events, complete with appearances by the Marco Andretti. Testimonials from patients also promote products to families. A mom is quoted on one CSL Behring website: "We've found that being comfortable with the pharmaceutical company can be just as important as being comfortable and happy with the actual product...The manufacturer of Helixate FS has always provided a very strong support system, from the old days when the company was Armour, going right through to CSL Behring." The focus is again on extrinsic attributes: the company's reputation despite several name changes.



“Shift to the fast lane...”
Smaller volume means convenience
(Bayer HealthCare)

Other extrinsic attributes include peel-off labels and vial etchings to allow fast tracking of inventory and prevention of theft – first instituted by Grifols. *Heritage*, or a company’s history of accomplishments and firsts, is also an attribute. Consider Baxter’s many firsts: first commercially available factor VIII product, first heat-treated factor VIII product available in the US, first monoclonal purified factor VIII product, first recombinant product, first third-generation factor VIII, first electronic logging system, first 3,000 IU vial size. Wyeth produced the first (and still only) recombinant factor IX. Novo Nordisk marketed the first recombinant factor VIIa product.



“Boys will be boys”
Muddy sneakers mean liberation and a more normal life
(CSL Behring)

Novo Nordisk emphasizes social consciousness as a company attribute. “It’s what we call the ‘triple bottom line,’” explains Klaus Davidsen. “We are actually not owned by shareholders in the traditional sense. We are owned by a foundation whose sole purpose is advancing healthcare. So we can and must make decisions not focused just on profits.”

Convenience, assay size, packaging, programs, choice, company structure and background...all help to distinguish products from one another. But considering the brand loyalty of hemophilia patients, sometimes it takes a daring marketing campaign to encourage a switch.

Free Trials as DTC Advertising

One of the most daring and popular DTC tactics in the last two years is the free trial of hemophilia products. Offering free product samples is a kind of bait-and-switch. The obvious goal is to get consumers to switch to another product. Typically, a patient can order six free doses of a product, but only through his or her physician. Do free trials successfully sway patients to switch? And are they ethical?

“We’ve found legitimate promotions such as the free trial program to be very effective. It allows patients an opportuni-



“The clear choice”
A clear marble symbolizes no human or animal proteins
(Baxter BioScience)

ty to evaluate our product under medical supervision without having to make a commitment to changing products,” says Marianne Drysdale of Bayer.

It seems obvious that truly valuable breakthrough drugs shouldn't need heavy marketing – they should sell themselves. But drugs that are similar to each other need constant marketing because they are less differentiated. To differentiate products, manufacturers have created a vast array of programs for specific age groups, educational materials bearing company logos, and insurance programs to help patients maintain coverage. Product and company become associated in the minds of consumers *and* become differentiated from the rest.

Brands Gone Bad

Let's examine two notorious examples of advertising campaigns that caused the community to react strongly against DTC advertising: the Bayer Direct program in 2002, and Baxter's Emerging Pathogens campaign in 2005. Both caused credibility problems – not for the products, which are excellent, but for the companies.

Bayer Direct was originally designed to help loyal users obtain factor in case of shortages. The problem was that second-generation Kogenate FS was rolled out at the same time Bayer Direct was launched. Kogenate users could no longer order Kogenate, and were offered Kogenate FS instead, which was higher priced and available only through Bayer Direct, a specialty pharmacy program. The program was available only to the first 700 who applied. These sales tactics were high-pressured and emotional. Patients rebelled, and some abandoned Kogenate.

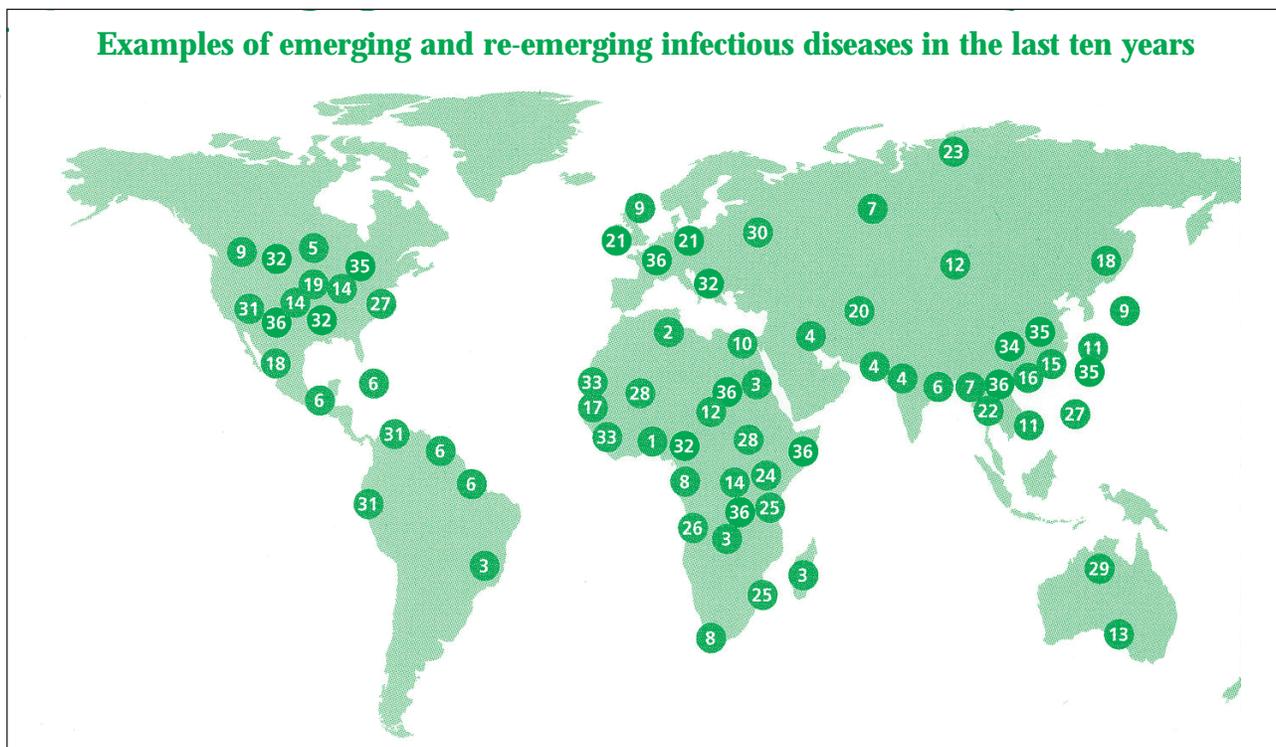
“We very quickly realized that this was a mistake,” admits Marianne Drysdale, “and we responded to our customers by terminating the program. This was a great learning experience that has taught us the importance of listening to our customers in advance of launching new initiatives. We have taken this to heart.”

The Emerging Pathogens campaign coincided with the West Nile virus scare of 2002. Baxter sought to position Advate as the “safest” choice, by insinuating that emerging and harmful viruses could eventually affect any product using animal or human products. The campaign appeared scientifically based, but in fact appealed to one emotion – fear. Ads featured swamps, and public presentations showed a map of the world, highlighting Africa as a source of emerging pathogens. The only problem was that Baxter, of course, was itself simultaneously selling plasma-derived and first-generation products.

“When we first launched Advate,” recalls Michelle Priefer, “we thought the potential for emerging pathogens was important, and we took an approach we thought was scientific, educational, and factually based. But the tone was scaring people. We listened to [the] community and we heard that we aren't approaching this the right way. The emotion of fear was being generated. We didn't intentionally seek to do this. We then shifted the tone from negative to positive by speaking to the benefits of eliminating risk and the ease-of-use enhancements.”

She adds, “When an emotional approach is used, it can be positive or negative; you run the risk of over-promising and under-delivering. We need a balanced approach in marketing. This is an emotionally-driven community, and we want to tap into it, but not take advantage of it.”

Emotional marketing runs risks: Baxter used this WHO graphic when it launched Advate



What to look for in a DTC ad

What should a consumer look for in a DTC ad? Ask yourself these questions:

- Who is the intended target?
- How is this product different from or better than the one I am using?
- Does the ad elicit a strong emotional response from me? Is that response positive or negative?
- How does that emotion correspond to facts about the product?
- Is this product positioned as a breakthrough? Is it truly breakthrough, or just enhanced?
- What product attributes does the ad promote? Are they extrinsic? Intrinsic?
- Do I need or value these attributes? Are they important to me?
- Are the possible side effects clearly stated?
- What do I know about the company that manufactures the product?
- Have I read the product inserts?
- Have I spoken to my hematologist and HTC staff about this product? What do they recommend?

What to ask your doctor

When your doctor prescribes or recommends a new drug, Dr. Marcia Angell advises you to ask these questions:

- What is the evidence that this drug is better than an alternative drug?
- Has the evidence been published in a peer-reviewed medical journal, or are you relying on information from drug company representatives?
- Do you have any financial ties with the company that makes this drug (company stocks, fees for consulting, member of advisory board)?
- Other than free drug samples, do you receive gifts from drug companies?
- Are you being paid to put me on this drug and enroll me in a drug-company study?

Should Pharma Use DTC Marketing?

Pharmaceutical companies are not free to advertise whatever they want; even the Emerging Pathogen campaign was FDA approved. Marketing practices of the pharmaceutical and biotechnology industries are highly regulated by the FDA. Still, Dr. Marcia Angell notes that in 2001 there were only 30 FDA reviewers to cull through 34,000 DTC ads. Obviously, mistakes will be made and inappropriate ads will slip through the cracks.

Perhaps for this reason, manufacturers have internal review procedures as well. "In all of our marketing initiatives, Bayer HealthCare has an extensive and thorough internal legal, medical and regulatory review process to ensure that the materials that we provide are relevant and valuable," explains Marianne Drysdale. And Kim Tully of CSL Behring notes, "There are federal and state restrictions that govern our activity, and we must be compliant. We know what the guidelines are, and [we] stay within those guidelines."

Manufacturers are not allowed to collect individual and personal patient information. "We don't have access to any patient addresses and names," says Michelle Priefer. "There is a Privacy and Security Officer at Baxter who approves all of our marketing programs to ensure privacy and security." Klaus Davidsen adds, "I do think there is value for consumers to receive information directly from pharmaceutical companies, but the information has to be valued, and appropriate."

Debbie de la Riva is executive director of the Lone Star Chapter of NHF and the mother of a child with hemophilia. Her chapter prohibits DTC product mailings and has strict policies about how pharmaceutical reps should interact with families at local events. But as a mother, she welcomes direct advertisements, especially if they are educational. "I want to know what's available out there to make an informed decision, along with my physician."

Debbie's point raises the greatest worry about DTC marketing. Michelle Priefer explains: "With a chronic disorder there are no limits to the education and knowledge you need. But marketing should be done where patients should have dialogue with their physicians. If not done properly, DTC marketing can interfere with the doctor/patient relationship."

In her book Angell writes, "Direct-to-consumer advertising should be prohibited in the United States just as it is in other advanced countries." She has valid concerns, but her stance flies in the face of our American culture, and perhaps

Bayer HealthCare



"We've found legitimate promotions such as the free trial program to be very effective."

—Marianne Drysdale, senior director, product management, Kogenate FS, Bayer

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CSL Behring Launches “Local Empowerment for Advocacy Development”

The new LEAD program will allow CSL Behring to partner with local patient organizations to pursue advocacy initiatives. The program has two specific initiatives: LEAD grants, at \$10,000 each, will help promote and develop advocacy on the local and state levels. Raise Your Voice! is a youth advocacy training program to introduce 16- to 23-year-olds to advocacy. It will be administered in collaboration with local patient organizations and sponsored by CSL Behring, and held at a state capital or in Washington, DC.

For information: www.cslbehring.com/leadgrants

Transition Tool for Young People with Hemophilia



Road To Pro Moves (RPM) is a helpful kit that provides educational tools for transitioning teens and young adults to help them cope with daily social challenges of living

with hemophilia. Through a series of age-appropriate illustrated brochures, RPM's graphic-novel storytelling brings to life everyday issues such as self-advocacy, self-esteem, social support, career options, starting work, and insurance. Produced by Baxter BioScience.

For information: contact your HTC

New Online Resource for Tracking Infusions

Bayer HealthCare introduces EZ-Log Web Client, which allows patients and clinics to record and track treatment using the Internet. This online resource is available to all hemophilia patients, regardless of which product they use.

For information: www.kogenatefs.com/patients_EZLog.cfm

New Third-Gen Factor VIII Product: Xyntha

On February 21, 2008, Wyeth Pharmaceuticals received FDA approval for Xyntha™ (ZIN-tha), its new recombinant factor VIII product for patients with hemophilia A. Xyntha is designed for both the control and prevention of bleeding episodes, and for surgical prophylaxis. Xyntha is the only recombinant factor VIII product to use an entirely synthetic (non-human and non-animal-based) purification process in its manufacture. Until now, the purification process for all recombinant factor VIII products used monoclonal antibodies derived from mouse cell lines. In Xyntha's manufacture, the mouse monoclonal antibody is replaced by a synthetic peptide ligand, invented by Wyeth scientists. Xyntha should be available to patients later in the year.



For information: www.xyntha.com

Monarc-M Production to Cease

Beginning in 2008, Baxter will discontinue production of Monarc-M, one of its two plasma-derived factor VIII products. Baxter believes that “consolidating our efforts to one plasma-based therapy offering will help improve availability of current dosage strengths.” To ensure a smooth transition, Baxter will make Monarc-M available for about 12 months based on current demand.

For information: 1-800-423-2090

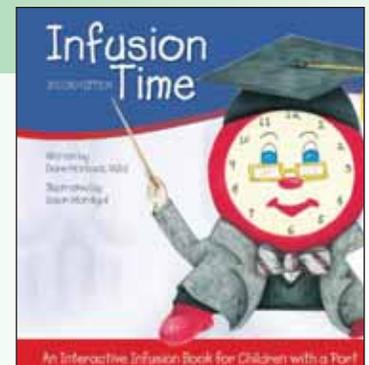
Home Care

Hemophilia Health Services: Infusion Time

The second edition of *Infusion Time* is the latest educational resource from Hemophilia Health Services. Written by Diane Horbacz, MEd, the updated book keeps the fun, rhyming text and interactive tools that teach children about port infu-

sion. Illustrations by Susan Mordigal, mother of a child with hemophilia.

To order: 1-800-289-6501 ext. 05145
Heal@HemophiliaHealth.com or
www.HemophiliaHealth.com



NHF Walk to Raise Money

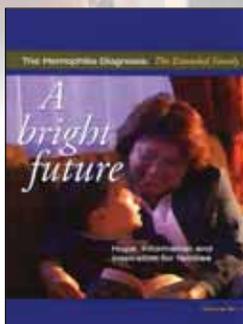
NHF will hold the Hemophilia Walk, its first national fundraising and awareness campaign, on June 1 in New York City. Walks are also scheduled in four other cities: Houston, September 6; Cleveland, September 20; Phoenix, September 28 (tentative); Raleigh, NC, October 18. Presented nationally by Baxter BioScience.

To register: www.hemophilia.org/walk or John Indence, 212-328-3763

New DVD for Families with Hemophilia

A Bright Future Vol. 2, "The Hemophilia Diagnosis: The Extended Family," focuses on how the diagnosis affects more than just parents and siblings. This DVD also demonstrates how hemophilia is genetically transmitted, offers advice and suggestions for more effectively managing the diagnosis, and provides resources for extended family members. Available free of charge. Funded by Baxter BioScience.

For information: Inalex Productions, www.inalex.com



PROJECT
SHARE

It's time to give back.

Project SHARESM Donates 3 Million IUs Overseas

Project SHARE donated about 3 million IUs of factor to 50 countries, including four new recipients: Ethiopia, Senegal, Surinam and Palestine. Patients who otherwise would never have received help include Angelo, of the Philippines, who received 388,000 IUs of inhibitor product for emergency abdominal surgery; and George, of India, who needed 190,000 IUs of inhibitor product for a life-saving leg amputation and post-op therapy.

Project SHARE is a humanitarian program of LA Kelley Communications, Inc.

To learn more: www.kelleycom.com/projshare

Hemophilia Federation India Achieves Major Goal

The Delhi High Court acted on a public interest litigation filed by Hemophilia Federation India (HFI), which highlighted the dire absence of life-saving drugs for patients in Delhi. The court designated the Lok Nayak, Deen Dayal Upadhyaya Hospital, and the Guru Tej Bahadur to provide treatment free of cost for people with hemophilia who are below the poverty line, and for those who urgently need medicine.

For information: hfindia.org/node/124

Science

Mice "Cured" of Hemophilia

Transplantation of healthy liver endothelial cells into the livers of hemophilic mice "cured" the disorder, according to US investigators at the Albert Einstein College of Medicine in New York City. Three months after the transplantation of cells identified as those responsible for producing factor VIII, the number of cells had increased, and the cells were secreting factor

VIII in amounts sufficient to resolve the condition in this mouse model of hemophilia. According to the lead investigator, this is the first time a cure has been achieved with cell therapy. The report appeared in the February 14 online edition of *Journal of Clinical Investigation*.

Source: *International Blood and Plasma News*, Feb 2008

Inbox... continued from page 2

I HAVE TWO BOYS WITH TYPE 2M VON WILLEBRAND DISEASE.

One also has a platelet dysfunction and has been on prophylactic infusions of Humate-P® since age three. I have been reading *PEN* for years and appreciate all your efforts on behalf of the bleeding disorders community.

I thought that your readers might be interested in how we are using emerging technologies to solve challenging blood supply problems. I am the assistant director of the E-Business Consortium at the University of Wisconsin in Madison. We house a state-of-the-art radio-frequency identification (RFID) lab that allows us to undertake research projects with companies throughout Wisconsin and in certain cases, throughout the US. RFID is an automatic identification method, relying on storing and remotely retrieving data using devices called RFID tags or transponders. One of our recent research projects has been with the Milwaukee-based Blood Center of Wisconsin to determine if the use of RFID technology can help to make the blood supply safer. One day the knowledge gained will benefit hospitals and patients throughout the country, and perhaps beyond. The story at www.news.wisc.edu/14812 was immediately picked up by *Computer World*. Several times a week, the issue of a safe blood supply comes knocking at my door in the form of factor for my youngest son, and the concern is always there in the back of my mind. With this technology, we may be one step closer to making the whole issue less of a concern for thousands of people every day.

✉ **Beth de Garcia**
Asst. Director of Member Relations
UW E-Business Consortium
Wisconsin

AS THE TEENAGE SISTER OF A BROTHER WITH HEMOPHILIA, I remember occasionally picking up *PEN* from the kitchen counter and perusing the articles. I was always interested in reading about my brother's blood disorder and the scientific advances being made. But after growing up and moving several states away, I no longer stayed abreast of what was happening in the hemophilia community.

That quickly changed when I became a mom and discovered that my son had hemophilia. Luckily, I had great family support and a wonderful HTC to get me up to speed. I was thankful to learn that my son would not endure many of the things that my brother did.

As the years passed, I learned how to infuse, educate the school, and advocate for my child. So in many ways, my family history prepared me for my future motherhood. But one issue kept reappearing that I didn't recall with my brother.

My son continues to struggle with the idea of being "different" from other boys. Although he learned to deal with and accept his infusions, he refuses to accept limitations – mainly sports restrictions. Perhaps my brothers had an easier time understanding the consequences of taking risks; they had frequent ER visits with lengthy infusions of cryo. Or maybe it was the fact that they didn't have an HTC with knowledgeable doctors and were often greeted and treated as a frightening anomaly. Maybe these experiences helped them gain a healthy fear of taking unnecessary risks.

With my son, I've experienced many teary nights with sobbing pleas: "It's not fair," "Why did I have to be the one in the family to get hemophilia?" And my least favorites: "But I love football. Why are you doing this to me?" and "I promise I'm not going to get hurt."

So what is the formula for sports-enthusiastic boys with hemophilia who are passionate about "unacceptable" sports? How do you help your son feel strong while helping him understand that he can't participate in some of the things that other boys do? How do you develop healthy boundaries while helping him avoid the feeling of being cheated? How do you convince him that even though he hasn't had a bleed in several weeks, he will likely get one if he plays football? I don't know that you can.

Next year, my son will be in seventh grade, and the school will offer organized sports. I'm sure my son will try out for basketball, but I'm also sure I'll receive the desperate plea for football. If anyone has experienced a similar issue and would like to share their advice, I welcome the feedback before my next conversation or – more accurately – next battle.

✉ **Colleen Lister**
Virginia



Lister family

Eric Lister:
It's hard to accept limitations

The Creative Frontier, Inc.



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I CAME ACROSS A PRODUCT FOR households with children. It's a godsend for parents, grandparents or caregivers of those with hemophilia. It is a mesh gate that doesn't pinch or give splinters. I sure wish this had been around when my son was born. Retract-A-Gate is a small company that I hope you will check out. Thank you for all your efforts. They are more appreciated than you will ever know.

To order this product, visit www.retract-a-gate.com.

Lee Trotter
Illinois

I JUST WANTED TO THANK YOU FOR GETTING IN TOUCH WITH me nine years ago when Jacob was a baby. You made such a difference in my life. Throughout the years, I have given the books you sent us to teachers and school nurses, and you have made it so much easier on all of us. My cousins are finally being tested as they are pregnant with boys. I'm hoping that if they are carriers and have boys with hemo-

philia, they will be able to benefit from your generosity and knowledge as well.

✉ **Marcie Reynolds**
California

THANK YOU FOR THE FOURTH EDITION OF *RAISING A CHILD With Hemophilia*, which we received last week. It will be a fantastic resource for us, and I love the accounts from other families. It also makes me so grateful that we have the National Health Service (NHS). When I look at health insurance in the US, we are very fortunate here!

As I write this, snow and gale-force winds batter at the windows. We live on the Shetland Isles, a small collection of islands that lie more than 200 miles across the sea from Aberdeen, UK – our nearest HTC. We are at latitude 60 degrees north; arctic alpine plants grow here, but no trees! The scenery is stunning and includes some of Britain's highest cliffs, hundreds of sea caves, wide open sandy beaches, and sheltered sea lochs. In summer, we see the "simmer dim" when the sun dips below the northern horizon for a little while. In contrast, the winter days have fewer than six hours of daylight.

The downside is that it's cold and very remote. The ferry and plane are very expensive, and we have left the island only once as a family since coming here. We do go to the mainland for hospital appointments in Aberdeen (the health board pays for flights), and we make the most of the shopping opportunity! We moved here nearly five years ago from Cardiff, the capital of Wales, where we lived a mere four miles from our HTC! When we moved we knew our eldest son, Yoel, had severe hemophilia A. He had a circumcision at 14 months and nearly bled to death afterwards. With a hemoglobin level of three, Yoel had to be resuscitated, and the hemophilia was detected.

Since then we have discovered that three of our four girls also have bleeding disorders. Ellie, nearly four, is a

Yoel Howard: Life with hemophilia on a remote island



photos: Jan Howard

Howard children (left to right): Hannah, Esther, Ellie, Abigail, Yoel



symptomatic carrier of hemophilia, with 16% factor VIII levels and low (39%) von Willebrand factor levels. She has had severe bruising from minor bumps; knocks on her head have caused bruising over her eyes and face lasting for six weeks. We give her DDAVP at home. Seven-year-old Hannah, while not having a bleeding disorder, has a neurological condition that the doctors initially thought was cerebral palsy. But her symptoms have worsened, so she has been referred to the pediatric neurologist for more tests. Abigail, age five, has low factor levels (24%), but normal VWF. When we told her about her mild hemophilia, she was actually pleased and did a dance! I think she may have been feeling a little left out that her siblings had medical problems. Esther, age 21 months, has low levels of VWF, but her factor VIII is okay at 61%. We seem to spend a lot of time at the hospital with our kids – Ellie even thought it was our second home! They are happy, though, and don't let their conditions affect life too much.

Yoel has had a difficult couple of months, as his veins have been difficult to access. As a result, we have not been able to give him prophylaxis at home or in the hospital. He has had several ankle bleeds – one was the worst he's ever had and lasted a week. His whole foot and ankle were swollen, and for the first two nights he was awake all night in pain. We did get on top of it eventually with twice-daily infusions, but it gave me an insight into what life would be like without treatment and how lucky we are to have factor when we need it.

Shetland can be very isolating at times if you have a child with a chronic medical condition. Bad weather frequently cancels planes or ferries. This can mean delays in getting medical supplies to us, and also delays in traveling to the mainland for treatment. The local hospital – the only one on the island – is a 50-mile round trip. At the end of last year, we were making this trip regularly several times a week, as Yoel had joint bleeds and poor venous access, and we needed to get his factor infused. Since January he has had a port, which means we can give treatment and prophylaxis at home. We still face times when we run out of supplies and have to wait for the next delivery, but the local hospital and children's nurse have provided fantastic support, and this has had a huge impact on how we have all coped as a family.

We decided to move to such a remote place because of my job as a health visitor. Before we came, we did contact another family with a boy with hemophilia who lives on the island. We have always felt, though, that hemophilia should not be the main thing driving our decisions. If it had been, I don't think we would have moved! There are obviously times when it does "take over" – if Yoel has a particularly bad joint bleed, for example. But these times are far outweighed by the benefits of living in such a lovely place. The community is very strong, and it's a safe place to bring up children – we rarely lock our house or car! I think that our attitude of accepting the kids' medical conditions has a positive effect on them: they don't see it as a problem, but have an attitude of just getting on with life. They even look forward to hospital appointments as it means a plane ride to Aberdeen. We feel very lucky to have such great kids and enjoy the challenges of living in this remote place.

✉ **Jan Howard**
Shetland Islands, UK

Storm Watch... continued from page 6

external pharmacy may retain the increased profit they receive by obtaining volume discounts in acquisition pricing instead of passing the value on to their patients.

This strategy is validated by the fact that a number of national insurers have created their own in-house specialty pharmacies in the last three years, and many more are moving to “exclusive” provider contracts for hemophilia factor.

4. What impact is PrecisionRx having on the community? On reimbursement costs? Why is WellPoint forcing hemophilia patients to switch to PrecisionRx?

PrecisionRx Specialty Solutions, WellPoint’s specialty pharmacy, is having a favorable impact on the community. For members who have transitioned to PrecisionRx Specialty Solutions in California, we have seen a 25% reduction in the total costs of care when compared to the previous

providers’ billed charges.

The savings resulted from a lower unit drug cost, 2% assay targets, and by not billing per diems for a self-infused medication. The data thus far suggest that the transitioned members may enjoy a significant extension of their lifetime benefits.

WellPoint is not forcing members to PrecisionRx Specialty Solutions. Members can choose to utilize a 340B center for factor, for example. But by limiting the provider network dispensing hemophilia factor, WellPoint will gain consistency in treatment protocols, improved best-in-class pricing, and optimal clinical outcomes.

By achieving these results, WellPoint is striving to increase the affordability of healthcare and improve the wellness of the members we serve. ☺

If you are a WellPoint member and have a question about your hemophilia service, please call 866-468-5787.

Pharmaceutical DTC Marketing... continued from page 14

even our Constitution. As recently as 1976¹⁴ the US Supreme Court extended First Amendment (right to free speech) protection to commercial advertising.¹⁵ In that particular case, the court declared unconstitutional a law banning all prescription drug price advertising. Justice Blackmun stated that the individual consumer and society desire the free flow of commercial information, including that from pharmacies. In his summation, he concluded that “people will perceive their own best interest if only they are well-enough informed, and that the best means to that end is to open the channels of communication rather than to close them. It is precisely this kind of choice between the dangers of suppressing the information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.”

First Amendment aside, DTC marketing, although core to American consumerism, is appropriate to use in promoting factor concentrates *only* when hemophilia patients are educated about pharmaceutical marketing tactics, can identify how and why they

are being targeted, know the right questions to ask about products, know their hematologist’s relationship with pharma, and always consult with their HTC hematologist before considering a product switch. Ads can educate as well as influence, so parents and patients need to be proactive and savvy. Parent Shari Bender agrees: “I didn’t switch products due to any particular advertisement. I switched only after speaking to my hematologist and after speaking to another parent already using the product I was interested in.” Independent and empowered hemophilia patients are the goal. Consumer education, awareness and collaboration with the HTC will ensure a product choice that meets the patient’s comprehensive needs. ☺

Shari Bender



Shari Bender: This mother’s product decision is not affected by ads

¹⁴ Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976). ¹⁵ DTC pharma print ads in the US began in 1985 and TV ads in 1997 when the FDA lifted the ban on such advertising.

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