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Generic Medical Devices Are Closer Than They Appear

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What if a significant portion of a $200 million segment of the medical device market were to go generic? Generic Medical Device (GMD) launched a Universal Sling System™ for female stress urinary incontinence (SUI), a class II medical device, during the summer of 2009. Market research indicates that 33% of physicians are sensitive to price. Therefore those physicians might consider using a "generic" device rather than a brand.

In terms of which types of medical devices of an estimated $200–250 billion global medical device market[1] can go generic, class II medical devices are probably the most vulnerable. Generic producers will target class II devices that that are not currently sold as commodities, but in reality the market would find it is hard to differentiate one branded product from another. Like the incontinence sling above, the initial generation of generic devices to enter the market will likely be mechanically simple. Generics "will also never fly" with more complicated products, says Lisa Sasso, Medical Development Group Board of Directors and President of Medical Development Partners.

Nonetheless, "simple" can still add up to a large chunk of device manufacturers' revenue. In the US alone, class II medical device revenue from the 19 largest medical devices represents approximately 10% of global medical device revenue, an estimated $26 billion of revenue in 2009.[2]

According to the FDA, "There is no such thing as a generic medical device that is equivalent to the meaning of 'generic drugs.' " A "generic medical device" does not have a regulatory pathway like a generic drug and it is not a commonly used term in healthcare. Despite the lack of FDA acknowledgement or official label, lower-cost generic medical devices are one sector of the healthcare industry that is likely to grow due to economic pressures. A generic asthma albuterol inhaler is an example of a "generic medical device" that manufacturers have developed. There are other types of devices, such as the female urinary incontinence sling, that are likely to grow in their respective markets.

Given the economic pressures on healthcare worldwide and generic products appearing ready for sale, why has the health-conscious market not embraced such devices? One reason appears to be the group purchasing organization (GPO). The funding relationship between the hospital GPO medical device distribution channel and

[1] Outsourcing Opportunities in the Medical Device (2009–2014) Markets and Markets 11/25/2009; Medical Market Fact Book, 2008 within Medical Devices Industry Assessment from the International Trade Association (www.trade.gov).

[2] Medical Technology Quick Comment: Senate Device Tax Takes Shape, Morgan Stanley, November 19, 2009.[3] Walsh, M.W., Senators Investigate Hospital Purchasing, New York Times, August 14, 2009.

medical device manufacturers has historically been a market force that can prevent lower-cost alternative treatments from entering the market. Typically, manufacturers who are selling products to a GPO can also be paying a GPO's operating expenses, which creates a conflict of interest. Government officials and the *New York Times* have scrutinized this funding relationship as a conflict of interest for years, and it is yet unresolved.[3] Further examination of market forces, such as distribution channels, pricing, technology innovation, and patents, allows one to understand why "generic medical devices" have developed and why they can continue to develop in the future.

History of Generic Drugs / Connection Between Generic Drugs and Devices

In trying to understand the idea of generic medical devices becoming more common, it is useful to look back at the history of generic drugs. Charlie Mayr, spokesperson for the Generic Pharmaceutical Manufacturers Association, explained that in the 1960s, the FDA instituted the Drug Efficacy and Study Implementation (DESI) program. For a number of years, the DESI program allowed safe drugs that had been around since the 1920s and 1930s to remain on the market, but did not have much science behind them. According to Mayr, "The term [generic drug] did not really exist until the Hatch-Waxman Act in 1984 and, prior to 1984, generic drugs were mostly a few antibiotics and there were also brand antibiotics." The Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, allows generics to obtain FDA approval by submitting less costly bioequivalence studies as part of an abbreviated new drug application rather than a new drug application. In the scenario of generic medical devices, despite not having a regulatory pathway like with generic drugs, Mark Leahey, President and CEO of the Medical Device Manufacturers (MDMA), comments, "There could be more manufacturers of similar 'generic' device technologies in 10–20 years because of expiring patents."

Lower-Cost Generic Medical Devices

GMD, a start-up company based in Gig Harbor, Washington, is developing generic medical device products. According to Shawn Lunney, GMD Vice President of Sales and Marketing, "GMD's mission is to develop and bring to market 'cost-effective equivalent' medical devices that provide equivalent outcomes at substantially lower cost." He continues, "GMD looks for products in the hospital that have a bad price/value balance and the next innovation in life cycle doesn't gain any [significant] patient value." Lunney says that generic medical devices are possible in all classes of medical devices, but simpler ones become commodities and physicians have more brand preference with sophisticated high-end devices.

[3] Walsh, M.W., Senators Investigate Hospital Purchasing, New York Times, August 14, 2009.

Generic Female Urinary Incontinence Device Gains Access To Branded Market With Entry Barrier Industry Force Decreasing

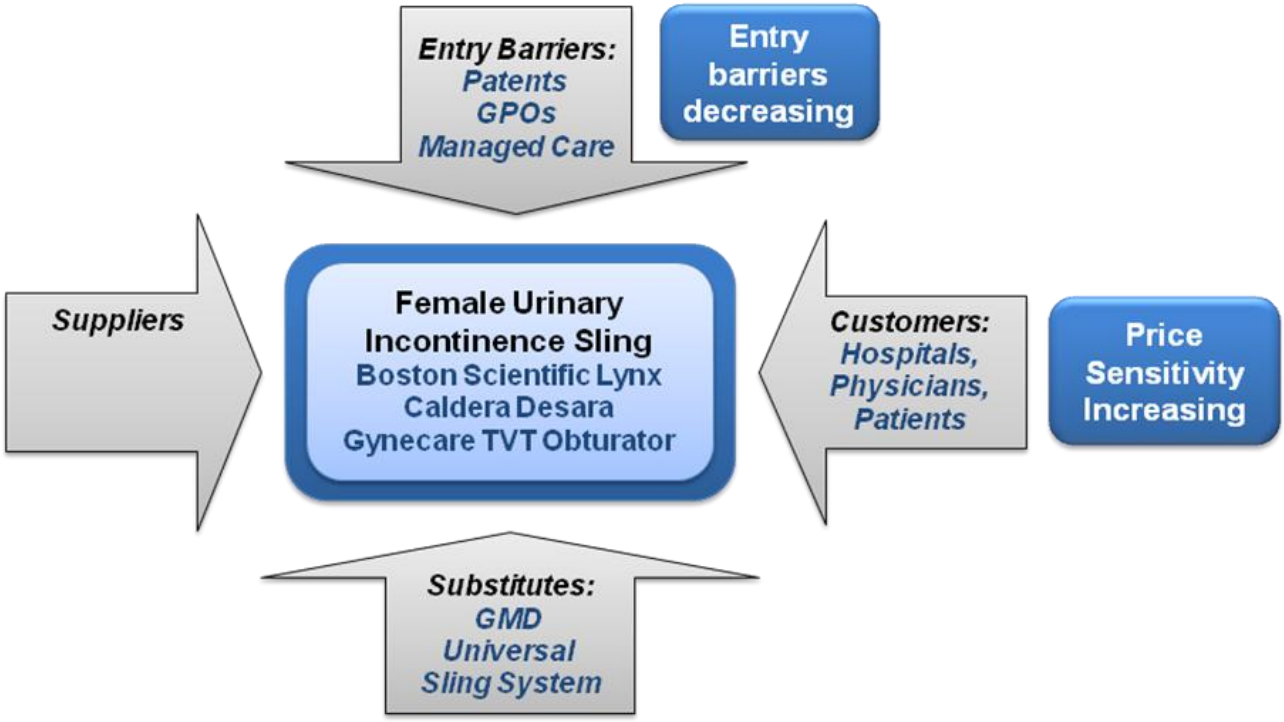


Figure 1: Expiration of patents, decreasing power of GPO manufacturer relationships, and interest from Managed Care, such as Kaiser Permanente, make it easier for a small substitute innovator, such as GMD, to enter a competitive market.

Source: Fuld & Company

GMD, focusing on the areas of urology and general surgery, launched the 510K approved Universal Sling System for female urinary incontinence in the summer of 2009. GMD's product competes with existing brand devices, such as Gynecare's TVT™ Obturator System, Boston Scientific's Lynx™ System, Caldera's Desara™, and Coloplasts' Aris and Supris. "The doctors seem interested and we are building commercialization," says Lunney. After a year on the market, GMD explains that organizations can save 25–50% by using their slings versus a branded sling. One Texas hospital reports a $50,000 savings after one year and other organizations are saving approximately $20,000 in a period of less than a year.

A search through the published medical literature over the last few years reveals a number of peer-reviewed papers that also support the idea that female urinary incontinence sling devices are similar and therefore invite generic substitutes. Pallavi Latthe, a urogynecologist of the Birmingham Women's NHS Foundation Trust in the UK, has recently reviewed clinical research of transvaginal versus transobturator tape procedures for SUI.[4] According to Pallavi, "The random sampling of mostly type 1 monofilament

[4] Latthe, P.M., Singh P., Foon R., and Toozs-Hobson P., Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials, BJU Int. 2010 Jul; 10 (1):68-76. Epub 2009 Nov 12. Review.

macroporous meshes in my study did not affect the short-term equivalent effectiveness comparing TOT and TVTO procedures." Pallavi explains that the random sampling of meshes included brands from Ethicon J&J, American Medical Systems' Monarc, and Mentor Porges' Obtape/Uratape, as well as others.

Sue Ross, Director of Research, Department of Obstetrics and Gynaecology at the University of Calgary,[5] also explains that female urinary incontinence meshes are somewhat generic. She comments, "I wouldn't say that all meshes were exactly the same, but I wouldn't be able to say whether the differences are real or whether they are all 'marketing' differences." She continues, "I believe the types of mesh used are fairly standard across the world [and] the manufacturers are all multinational, [although] there could be some local variation."

The asthma inhaler is an example of a generic device that first entered the market 15 years ago and did become a dominant product on the market. Since the mid 2000s through the end of 2008, 96% of the 50 million chlorofluorocarbon (CFC) albuterol inhalers being consumed were generic.[6] The CFC albuterol inhaler patent expired in 1989, but the first generic albuterol inhaler did not enter the market until 1995 because it took the FDA five years to develop asthma inhaler generic device bioequivalence standards. For the next 13 years, several companies including IVAX, Glaxo Smith Kline (formerly Glaxo Wellcome), and Warrick (former subsidiary of Schering-Plough) supplied the market with generic CFC albuterol inhalers.

However, due to environmental reasons and subsequent legislation, manufacturers had to withdraw CFC albuterol inhalers from the market by the end of 2008. Today, patients have to use the newer hydrofluoroalkane (HFA) albuterol inhalers instead. Although the albuterol drug patent has been expired for over 20 years, the newer HFA albuterol inhalers are using a branded patented device and are estimated to cost approximately $25–35 more than the previous generic CFC albuterol inhalers.[7]

But generic HFA albuterol inhalers are on the way. According to Richard Dalby, Professor, Department of Pharmaceutical Sciences, University of Maryland School of Pharmacy, "I know of a few generic HFA inhalers in development and I can't imagine the generic HFA inhaler would come close to premium pricing once there is more than one on the market." The series of patents on the branded HFA inhalers is expected to expire between the end of 2010 and 2017. Dalby expects that a generic HFA albuterol inhaler will be approved, "but not by the end of 2010." Dalby also explains that he would expect the generic HFA albuterol inhalers to dominate that market similar to the way generic CFC albuterol inhalers did once there is more than one version of each brand product approved and sold. He continues, "Up to that point, the first approved generic has some ability to command a premium price."

Battling the Distribution Channels – One explanation why generic devices have failed to achieve market acceptance

[5] Ross, S., Robert, M., Swaby, C., et al., Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial, Obstet Gynecol., 2009, Dec;114(6):1287-94.

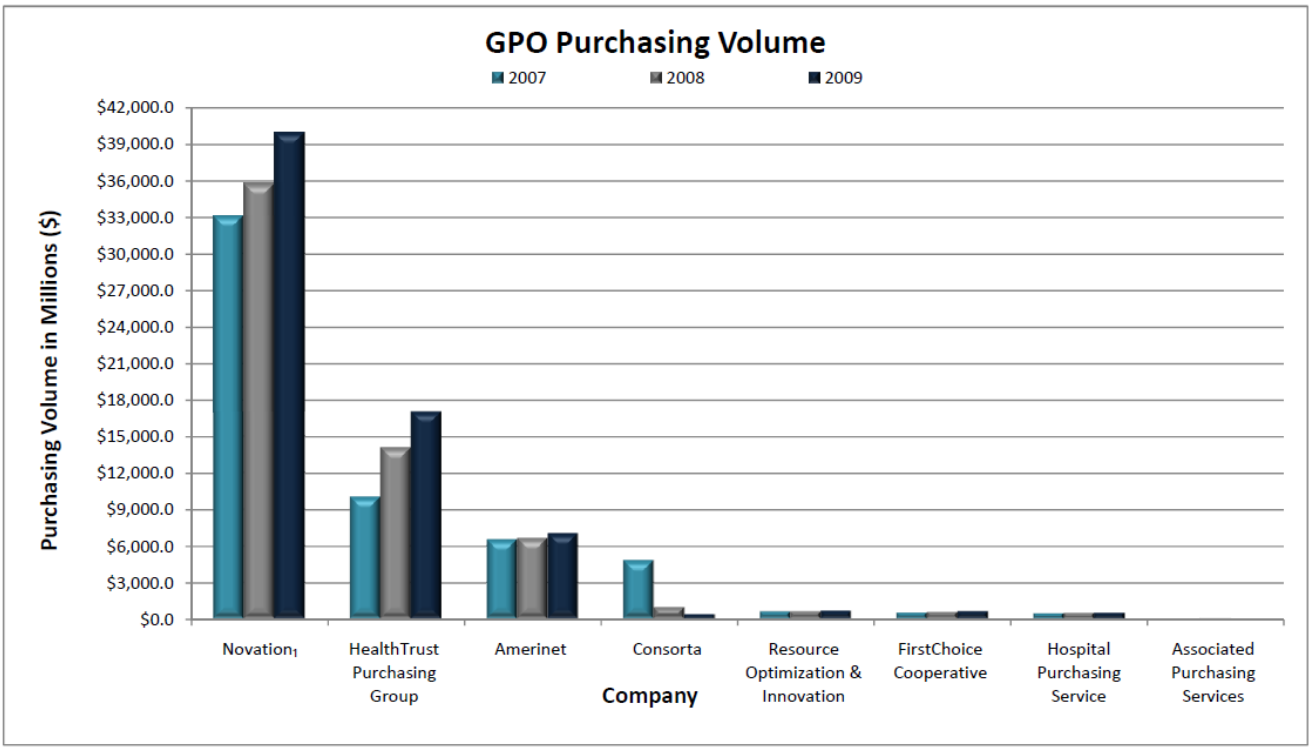
[6] FDA Register Volume 70(63), April 4, 2005.

[7] American Academy of Allergy & Immunology Website http://www.aaaai.org/patients/topicofthemonth/0507, May 2007, Patients and Consumers Topic of the Month.

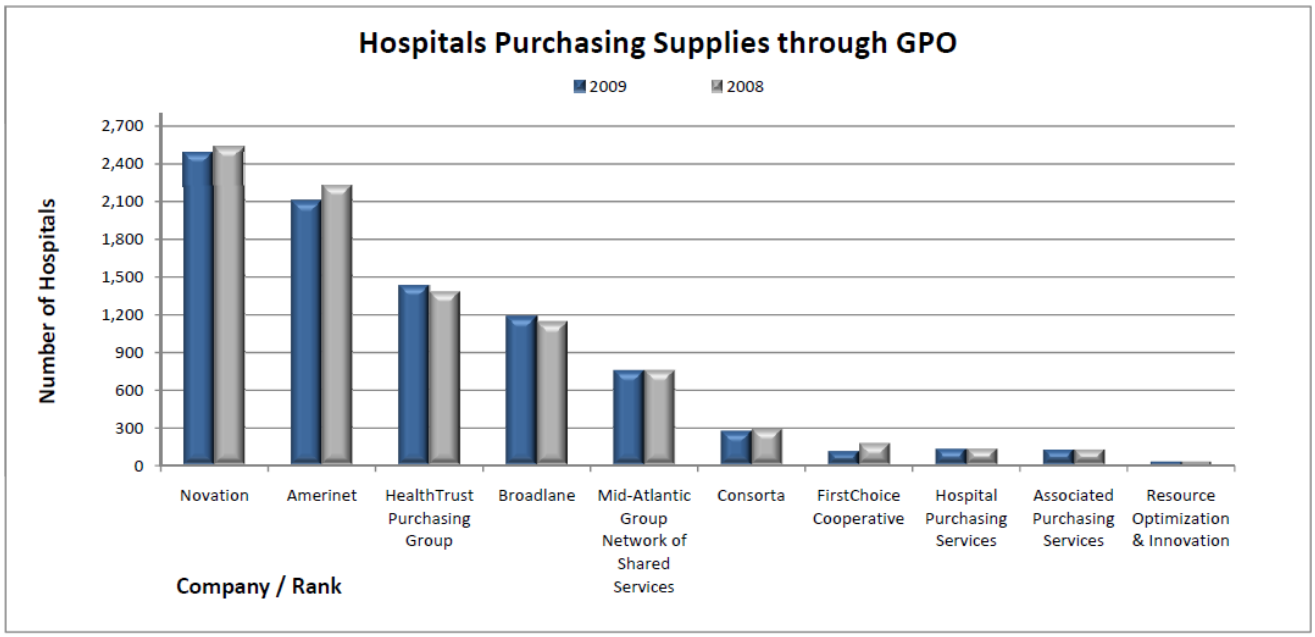
Regulatory approval of a generic device is, however, only part of the commercialization process. The ease of distributing a medical device through the various sales channels—for example to a pharmacy, doctor's office, or hospital GPOs—ranges greatly and can affect the commercialization success of a product. Sasso comments, "For some devices the point of sale is also a doctor's office and not just a hospital, which [can be easier] because there is not a pre-existing vendor matrix of 10–12 vendors." Sasso poses the question, "Why compete with the behemoths Boston Scientific, Medtronic, and St Judes?"

In contrast to distribution to a pharmacy or a physician office that may be a more direct point of a sale, distribution of medical devices to hospitals often goes through a GPO. Hospital GPOs have been in existence for over 100 years, but the system changed dramatically in 1986 and then again during the last 10 years. In 1986, the US Congress implemented the Safe Harbor Act system where suppliers can pay hospitals a fee in exchange for market exclusivity for their products. The idea behind the "safe harbor" is that the volume of purchasing would still save money. Leahey explains that the safe harbor of the GPOs kickback sets up "an inherent conflict of interest" to providing lower-cost options. During the last 10 years, several of the smaller hospital GPOs consolidated and created larger and more powerful GPOs that include Novation and Premier. *Modern Healthcare*'s annual GPO survey data of measures such as purchasing volume, membership, and financials, clearly shows that a few of the larger GPOs dominate the hospital GPO market.

The creation of the larger GPOs has caused the "safe harbor" and GPO kickback conflict of interest to be legally tested several times and continues to receive legislative scrutiny.



Source: *Modern Healthcare*'s 2009 Group Purchasing Survey



Source: *Modern Healthcare*'s 2009 Group Purchasing Survey

Generic pulse oximeter leads by Masimo are an example of innovative technologies that have had to battle with GPOs. In the spring of 2002, Masimo began working with the GPO Novation through a congressional committee to get its pulse oximeter product onto Novation's list of products. During July of 2003, while in the midst of the senate inquiry about GPO practices, Novation added Masimo's pulse oximeter to its product offerings. But, according to Leahey, "Only two weeks before Nellcor's [the existing market leader] pulse oximeter patent was to expire on November 15, 2003, Novation asked Nellcor (a Covidien business unit) to commit as a supplier for two to three more years." Thus, the Nellcor brand continued as a premium product with financial incentives tied to other products purchased when an alternative least costly product was also available. Subsequently, in March 2005, the Los Angeles Federal Court awarded over $400 million in damages to Masimo from Covidien (formerly Tyco) for an antitrust lawsuit with respect to GPO relationships and contracts.

Since then Masimo has been able to grow its business and develop relationships with several GPOs. The list of GPOs where Masimo distributes its products now includes Consorta, HealthTrust, Novation, MedAssets Supply Chain Systems, and Amerinet.[8] Approximately 4 years after the initial litigation and continuing appeals, Masimo reports that the price of pulse oximeters has decreased 30%.[9] In 2002, Covidien/Nellcor had 80–90% of the market, but their market share has dropped significantly since then.[10,11]

[8] GPOs May Spurn Anti-Competitive Contracts After Masimo v Tyco – MDMA, The Gray Sheet, March 28, 2005.

[9] Federal Court of Appeals Upholds Antitrust Liability Verdict Against Tyco HealthCare**,** www.masimo.com**,** November 2, 2009.

[10] Presentation to the U.S. Federal Trade Comission, Medical Device Manufacturers Association, September 10, 2002.

[11] GPOs May Spurn Anti-Competitive Contracts After Masimo vs Tyco MDMA, Gray Sheet, March 28, 2005, Pp. 11-12.

According to December 2008 and January 2009 Frost & Sullivan and iData market research reports, Covidien had 37.4–38.3% and Masimo has 37.4–43.5% of the total US pulse oximetry monitoring equipment market.[12]

After being a year in the market with its generic female urinary incontinence sling, Lunney explains that GMD is open to working with any customer, such as hospitals, ambulatory surgery centers, and GPOs, that want a lower-price device. "Although the Northeast GPOs have tough contracts, the Midwest, as well as parts of the South, are open, and Kaiser Permanente is an investor in the company," says Lunney. Kaiser's investment in GMD is an indication of hospitals looking for cost-effective solutions and makes the distribution barrier of entry easier for GMD. Lunney also notes that the power of GPO contracts has been diminished over the last few years with hospitals belonging to multiple groups.

Outlook for Generic Medical Devices

Generic medical devices do exist and can continue to grow. Several market forces, including changing distribution channels, increasing economic pressures, responsive legislation, patent expirations, and technology innovations, will act as catalysts toward acceptance of generics at a faster rate than ever before. Relatively simple devices, such as the female urinary incontinence sling and asthma inhaler, are evidence of where generic medical devices can develop. Patent expirations and scientific research studies demonstrating equivalent outcomes between brand technologies are indicators of where generic medical devices can develop.

Where a medical device is distributed—for example, a hospital versus a doctor's office—also makes a difference due to the potentially restrictive contracts hospitals can have with GPOs. The contracts may limit the products that are available or provide financial incentives to order one product versus another. There are cases of hospitals belonging to more than one GPO and smaller regional GPOs, such as the Colorado Hospital Association and Illinois Hospital Association, servicing hospitals.[13] However, the dominance of a few large national GPOs in the hospital medical distribution channels may be lessening, and evidenced-based medicine leaders such as Kaiser Permanente are likely to further erode the GPO contract lock on the market. Lastly, in the United States, the passage of the national healthcare reform legislation at the beginning of 2010 is expected to put pressure on all parts of the American healthcare system to contain and drive down the cost of healthcare, including medical devices.

[12] Masimo Corporation, 10-K, February 17, 2010

[13] Above beyond: Regional GPOs work to offer value, services that their national counterparts often don't provide, Modern Healthcare, August 2009, Pp. S1-S5.

Questions for product development to consider

As economic pressures continue to mount, medical device manufacturers need to consider questions about the market forces that allow the possibility of competing generic entrants.

1. **How novel is a manufacturer's product? What steps can the branded producer take to differentiate the device from succumbing to a generic substitute?**

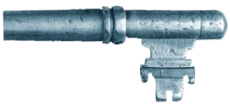
2. **How long will a patent yield any exclusivity?**

3. **Who are the likely new entrants in the medical device market? Will they come from the current crop of entrenched branded producers that choose to balance portions of their portfolios with generics, or will wholly new companies emerge, funded by venture capital?**

4. **At which point will hospitals abandon or be forced to abandon the GPO status quo? Will the Kaiser Permanente's of the world force the medical effectiveness issues on hospital purchasing decisions?**

5. **Does the GPO offer more than one comparable product to create competitive pricing? Will GPOs be forced to essentially create formulary offerings equivalent to managed care insurers who today place a generic alongside a prescription option?**

6. **Finally, what is the future profit picture for the class II device market? How will these companies manage or shift their portfolios in the decade ahead?**



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