

Pain Management Devices: Coexist or Supplant OTC Pain Medicines?

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Introduction

Pain management devices are increasingly used to treat chronic pain by consumers at home, having had prior healthcare professional (HCP) history of use, largely from chiropractors and physical therapists. These devices are used to treat body pain and include muscle and joint pain, but exclude devices for headache, menstrual, or rheumatoid arthritis/autoimmune pain.

There are two major forces at play that make the emerging pain management devices market attractive. First, consumers are increasingly incorporating technology, wearable devices, and gadgets into their everyday lives, which means consumer interest in these devices is being transformed from novelties to more mainstream solutions for pain. Second, people around the world are living longer than ever before. Longer lifespans translate into an increased incidence of pain and therefore, a growing need to prevent and alleviate such pain.

Pain management devices are not new as transcutaneous electrical nerve stimulation (TENS) technology



has been used for over 50 years by healthcare professionals. However, the market is witnessing an evolution of at-home TENS device use due to the retail introduction of products like Icy Hot Smart Relief TENS Therapy by Sanofi and Aleve Direct Therapy TENS Device by Bayer. Now that major pharmaceutical companies have entered this space and brought such technologies to the mass retail market supported by significant advertising and promotional budgets, several questions arise:

- Will these devices grow at a faster pace with increased mass retail presence?
- Will other large consumer healthcare companies enter this market?
- Will these devices have a negative impact on sales of OTC analgesics or can they coexist?

In this paper, Kline, in partnership with IRI, will answer these questions, drawing on findings from Kline’s recently published study ***Pain Management Devices: Global Market Analysis and Opportunities***.

Patients look “beyond the pill” for pain relief

An estimated 100 million Americans (or 1 in 3 adults) suffer from chronic pain, and about 50% of these consumers are not satisfied with current treatments, according to research recently conducted by Kline. These consumers tend to buy pain management devices from direct channels and online because they are seeking new technologies and products that will work for them. Conditions such as arthritis, fibromyalgia, sciatica, and neuropathy associated with diabetes are just some of the conditions that result in chronic

pain and reduced quality of life. At the same time, there is a crisis in America over addiction to prescription opiates and concerns about the risk of dependency when taking prescription pain medications on a long-term basis. Consumers are also concerned about long-term side effects associated with common OTC pain medications, including risks of stomach and liver damage. These trends have lead chronic pain sufferers to seek non-drug alternatives, such as pain management devices.

New technologies to keep an eye on

In the pain management devices market, there are three large groups of device classifications:

1. Those that work by **nerve stimulation or pulses (TENS)**
2. Those that use **light** to relieve pain
3. Those that deliver **heat** to treat pain

All TENS devices deliver **pulses and heat** which interferes with nerves’ transmittal of pain signals to the brain, thus mitigating the perception of pain. The pulses and heat delivered through TENS units are also said to stimulate blood flow to the area which promotes healing and can help the body release endorphins.

Light-based devices include those that use LED light, infrared light, low level light lasers, and polarized medical light. There are many suppliers offering LED light devices for anti-aging and acne because of the relative ease of gaining cosmetic device clearance compared to medical devices. However, LED light therapy helps release nitric oxide from cells which actually promotes healing on a cellular level, as opposed to just interfering with pain signals sent to the brain as TENS devices do. Light-based devices recorded the highest growth of all market segments researched at 18.0% due to growing consumer awareness and expanded distribution for these devices.

Popular Light-based Pain Management Devices



Biopton Light Therapy



Willow Curve



Revive Pain Relief LED Light Therapy



According to the U.S. FDA, cosmetic devices are used to improve appearance and do not impart any health benefits. The FDA classifies medical devices into three classes based on the risks associated with the device. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. For example, condoms are classified as Class II devices. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. For example, replacement heart valves are classified as Class III devices. Most of the devices discussed here are class II or class III medical devices.

Substantial research has been done on the use of light-based devices for various conditions, not just for pain treatment. Scientists at NASA have studied the use of **LED light** for years and its effects on treating blindness, macular degeneration of the eye, and treating side effects in cancer patients caused by chemotherapy and radiation treatments, among others. Research on the effectiveness of **polarized medical light** shows that consumers feel that these devices were effective for pain relief and other conditions. Devices that deliver polarized medical light penetrate deep into the body and actually stimulate the body to heal itself. They have also been studied for their ability to help wound healing and early results in this area are promising.

Significant financial investment would be required to

conduct clinical trials, gain FDA approval, launch, and sustain sales of a polarized medical light device. It is likely that only very large companies with deep pockets would be able to pursue medical device classification for such a device. Because of high costs of development and manufacture of such devices, polarized medical light devices would need to be sold at relatively high retail prices and therefore would most likely be sold via direct channels and HCP offices rather than mass retailers. A new polarized medical light device for pain management, wound healing, or other indications could mean improved quality of life for chronic pain sufferers and could seek coverage by insurers. However, these devices, given their high retail prices and appeal to only those with chronic pain, are not likely to be major market disrupters for OTC pain medications.

The therapeutic effects of **heat devices** include increasing the elasticity of collagen tissue, decreasing joint stiffness, reducing pain, relieving muscle spasms, reducing inflammation, aids in the post-acute phase of healing, and increasing blood flow.

- Heating pads have become a commodity product with 50% of the market being private-label products.
- Growth is slow at 2.0% with low innovation. The FDA defines heating pads as pads containing electrical heating elements with a removable fabric cover.
- They usually operate from household current and can be used to heat and treat sore muscles or joints.
- Popular brands include SunBeam (Jarden Consumer Products) and Soft Heat (Kaz).

Market growth drivers and trends

Sales of pain management devices in the United States recorded strong growth of 12.0% in 2016, which was much higher than OTC general pain relievers that grew by just 0.9%. Topical analgesics soared 15.8% in 2016 on the popularity of lidocaine line extensions to major brands. Topical and oral OTC pain relievers are more mature markets and are also much larger in size. Drug-free pain relief solutions are becoming increasingly popular among consumers, especially for those treating chronic pain, such as

arthritis, joint pain, or back pain, and who want to limit the amount of medication taken. According to Kline's attitudes and usage survey, U.S. healthcare professionals claim that among people suffering from pain, over one-third of people suffer from arthritis, followed by 15% that suffer from back pain. HCPs also increasingly recommend at-home use of pain management devices to their patients to treat arthritis and back pain.

Market drivers include:

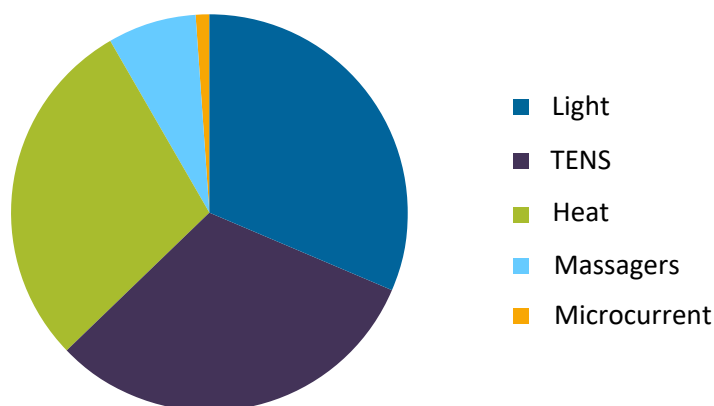
- 1. Increased incidence of pain in aging population*
- 2. Support by HCPs*
- 3. Lower side effects vs. oral medications*



Although pain management devices is the smallest segment of the analgesics market, strong growth recorded by these products indicates HCPs' willingness to recommend and consumers' willingness to buy and use these products. Devices appeal to consumers who may be concerned with possible side

effects from using internal analgesics, such as stomach upset or potential liver damage, especially when taken on a chronic basis. Pain medications, topical analgesics, and pain management devices are all part of a "cocktail" of approaches that pain sufferers use to get relief.

Market Share of Powered Pain Management Devices by Type in the United States

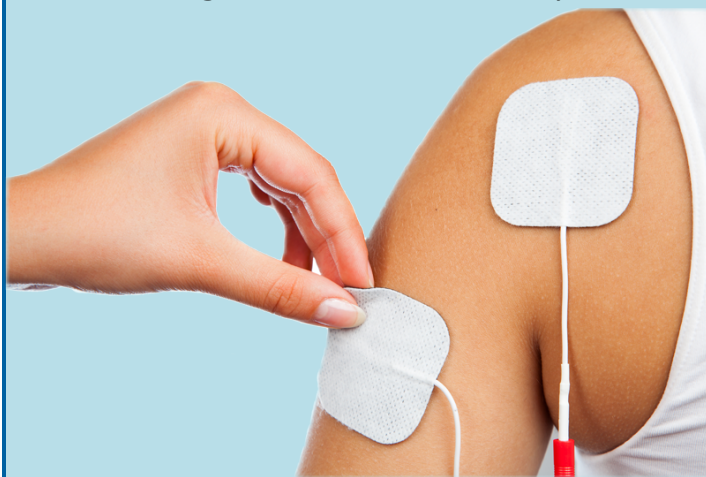


SOURCE: Kline's *Pain Management Devices: Global Market Analysis and Opportunities* study.



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Growth delivered.

At-home TENS devices are priced five to six times higher than OTC counterparts.



The average consumer who only suffers from minor, periodic pain is unlikely to invest in TENS or other pain management devices. The price points of these devices are much higher (often five or six times more) than OTC pain relievers. For example: Sanofi's tube of Icy Hot cream is sold for an average retail price of \$5.00 while the Icy Hot TENS device is sold for an average retail price of \$30.00. Similarly, a bottle of Bayer's Aleve is sold at an average retail price of \$10.00 while the Aleve TENS device is sold at an average price of \$50.00. Heating pads (Sunbeam and Soft Heat) are sold for an average retail price of \$25.00. Therefore, price-conscious consumers will likely continue to purchase OTC pain relievers given their affordability.

However, consumers who struggle with chronic pain may see the value in spending more money for an effective device that manages their pain for many years and reduces the amount of medication they need to take. Some consumers also like pain management devices because they generally have a professional and technologically advanced aura about them, which implies increased efficacy compared to OTC analgesics.

Given the nascent stage of the at-home pain management device market in the United States, consumers are likely to be confused about how the products work or skeptical about their effectiveness. Therefore, HCP and consumer word-of-mouth recommendations are crucial to the success of such products reaching critical mass. Infomercials on television that feature product demonstrations or online tutorial videos are also critical for increasing consumer awareness and purchases of pain management devices.

TENS Brand Examples: Icy Hot and Aleve

New devices offering alternatives to internal analgesics appeared initially on mass retail shelves next to topical analgesics in 2014. TENS devices have gained popularity with several new launches as these products grew by 12.0% in 2016. Sanofi launched its Icy Hot TENS device in November 2014. The new launch was backed by significant advertising and promotional dollars and a large-scale marketing campaign to raise consumer awareness and trial.

Sanofi spent about \$22 million in traceable media expenditures to support the Icy Hot TENS device

launch in 2014, according to Kantar Media. In addition, Icy Hot Smart Relief TENS was launched at a time when leading internal analgesic brands Tylenol and Motrin (Johnson & Johnson) and Excedrin (Novartis) were not back to full retail distribution because of each company's respective plant shutdowns. Therefore, Icy Hot Smart Relief TENS was able to capitalize on the fact that leading oral analgesic brands were not always available at retail. However, its time alone on retail shelves was brief, as there are private-label TENS units being sold at CVS and Walgreens.

The TENS entry from Aleve shipped in mid-2016, almost two years post that of Icy Hot. As illustrated below, sales of TENS devices are a small part of the overall Aleve franchise, with the Aleve Smart Relief TENS device accounting for less than 4% of dollar sales and less than 1% of unit sales in 2016, reflecting at best a half year of sales. Icy Hot Smart Relief TENS, which has been on the market longer, accounts for a larger percentage (24.9%) of total franchise dollar

sales, albeit off a smaller base than Aleve. The Icy Hot Smart Relief TENS device accounts for nearly 6% of unit sales of the Icy Hot franchise in 2016. This indicates that mass retail marketing of these products will take some time to build, and these brands could perhaps benefit from concurrent direct sales to demonstrate the benefits of the products more thoroughly and build consumer awareness.

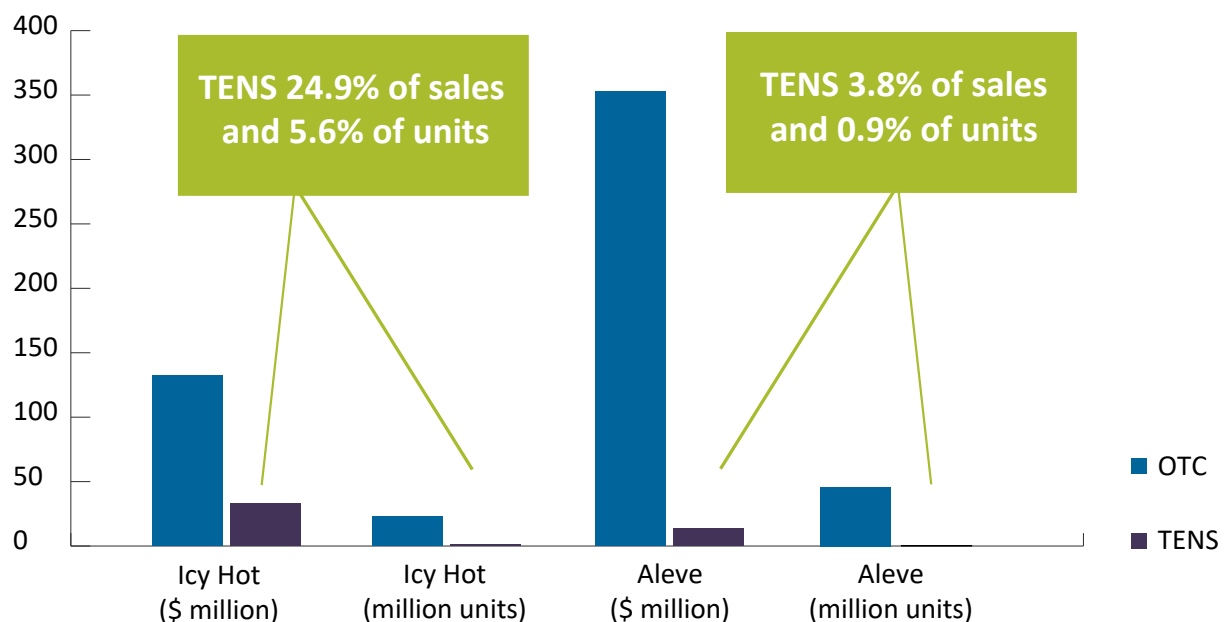


IcyHot Smart Relief TENS



Aleve Direct Therapy TENS

Sales of OTC Analgesic Brands compared to TENS Devices, 2016



SOURCE: IRI Retail Sales-Total U.S. Multi Outlet.



IRI
Growth delivered.

Another positive sign that there is room for both TENS and traditional OTC analgesics on the market can be seen with a brief look at growth of the Icy Hot franchise from 2015 to 2016. As shown below, topical Icy Hot managed to grow nearly 14% from 2015 to 2016, largely as a result of the successful addition of Icy Hot Lidocaine Cream in 2014, while the TENS product had

dollar sales growth of 5%, boosting the overall franchise by a solid 12.0% in 2016. While it is too soon to conduct a similar analysis of the Aleve franchise, it is fair to speculate that Aleve Direct Therapy TENS will grow by a strong pace and will account for more of the overall franchise's sales in year two on the market.

Retail Sales of Sanofi's Icy Hot Franchise, 2015 to 2016

	\$ Million		
Product	2015	2016	% Change
Icy Hot OTC	116.0	132.1	+13.9
Icy Hot TENS	31.3	32.9	+5.1
Total franchise	147.3	165.0	+12.0

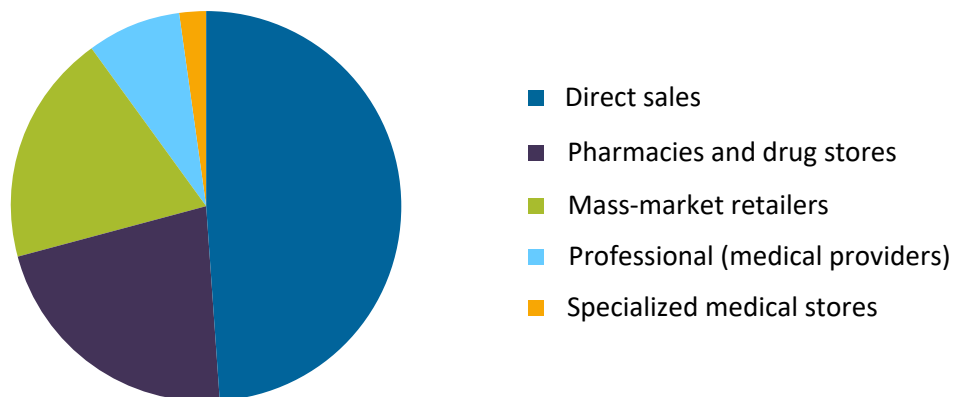
SOURCE: IRI Retail Sales- Total U.S. Multi Outlet.

Retail landscape

The retail environment for OTC general pain relievers and topical analgesics is crowded with several brands, SKUs, and products vying for consumers' attention. The introduction of pain management devices to the analgesics aisle at retail so far has not had a significant impact on sales of major brands in OTC categories, such as Advil, Tylenol, and Aleve. However, pain man-

agement devices come in larger packages than OTC analgesics and take up more shelf space, making retail pain planograms more crowded. Therefore, slower moving OTC or device brands with low or declining sales are at risk of being rationalized and removed from retail shelves.

Retail Distribution of Pain Management Devices by Segment and Channel



SOURCE: Kline's *Pain Management Devices: Global Market Analysis and Opportunities* study.

Popular Distribution Channels Selling Pain Management Devices

Direct sales

amazon



Drug stores

CVS

Walgreens

Mass merchandisers

Walmart



The direct sales channel is a key entry point for new devices/technologies.

- All manufacturers participate in online direct sales, whether that is direct from their own website or from an online retailer, such as Amazon.
- Some use direct sales exclusively, usually supplementing online sales with infomercials or home shopping, such as HSN and QVC.
- The direct sales channel continues to be a convenient way to reach consumers and is often informative with videos posted on the company's website or YouTube with demonstrations.
- Especially for new types of devices and technologies that are unfamiliar to most consumers, this offers the opportunity to demonstrate and explain how the device can best be used.
- For pain management device sales, the direct sales channel grows the fastest among retail channels at 15.5%.
- Direct sales of OTC medications remain a minor portion of overall distribution but, accounts for nearly half of distribution for pain management devices.
- Given that the retail channel mixes are so different for devices and OTC medications, these products are able to safely coexist, with room for both on the market.

Examples of Devices Sold Through the Direct Channel



LightStim Pain Device



Willow Curve



iTENS with Phone App

Device business model mimics razors

The bulk of revenues in the U.S. pain management device market come from repeat purchases of refill pads associated with TENS devices, and not the initial device itself. In fact, the FDA classifies the TENS unit as durable medical equipment, but the refill pads are considered consumables. In the past, HCPs such as physicians, physical therapists, and chiropractors would write a script for an at-home pain management device and patients could submit the prescription to their insurer for reimbursement. However, because of implementation of the Affordable Care Act, insurance coverage for pain management devices and refill pads has declined considerably from Medicare, Medicaid, and private insurers. This has lead consumers to seek self-treatment pain options and the convergence of pain management devices in the OTC pain relief aisle.

There are currently over 500 suppliers in the United States of pain management devices, but not all of these devices are approved as class II medical devices, which can be sold either Rx or OTC. There are several

devices that consumers may use to manage pain, but they are technically class III devices and are considered cosmetic, such as massagers, hot and cold packs, and wraps and braces. The road to approval for these cosmetic devices is much faster and less expensive than class II. With so many companies supplying the market through a diverse group of sales channels and under various levels of regulatory scrutiny, there have been several companies that have either been shut down by the FDA or have stopped marketing products in the United States due to suspicion of fraud. Gaining approval for medical devices is easier in Europe than in the United States so some companies focus on Europe only or market the device as a medical unit in Europe, but as a cosmetic unit in the United States.

Less insurance coverage, more consumers paying out-of-pocket, and the ability of other manufacturers and private-labelers to copy a device's design make this a cut-throat market in which to compete.

In general, consumers are not aware of these products or their benefits, so in order to sustain a successful brand considerable marketing dollars must be spent to educate consumers and retailers about benefits and features and to keep them coming back to buy refill pads. Competitors can easily benefit from another company's advertising spending to educate consumers about pain management devices.

Gaining FDA approval for class II medical devices is costly and time-consuming and likely to be pursued only by large companies that are able to invest in the clinical trials to prove safety and efficacy and to be able to sustain costly marketing efforts post-approval. The business model for success in devices is not sustainable for many small to mid-sized companies.

Conclusions

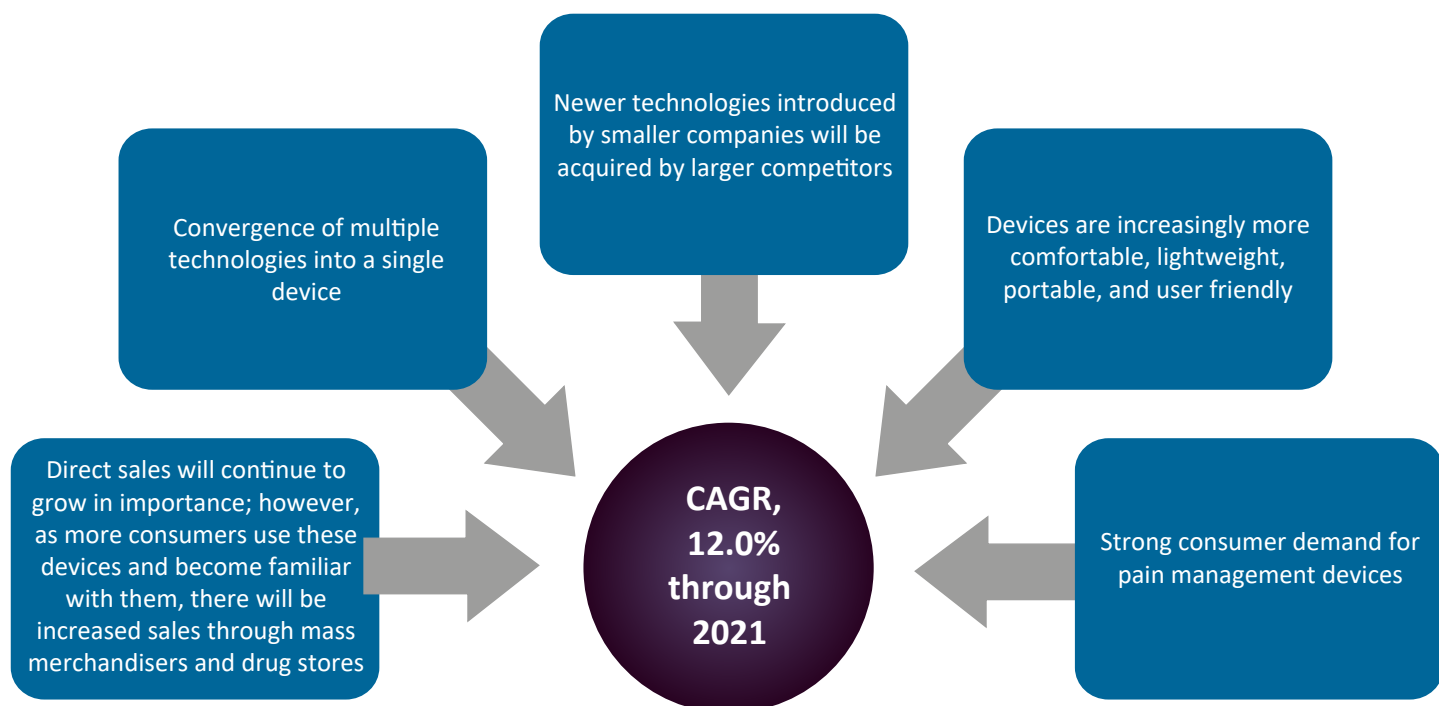
Pain management devices are expected to continue to outgrow general pain relievers and topical analgesics driven by popularity of devices, such as Icy Hot TENS and Aleve Direct Therapy TENS; however, they are not expected to have a huge impact on the OTC categories over the next five-year forecast period as general pain relievers and topical analgesics will remain the first choice for most consumers suffering from pain. In fact, we foresee many chronic pain sufferers continuing to use all these tools to help them mitigate pain and that at-home pain management devices will complement oral and topical analgesics.

Other leading OTC players, such as Johnson & Johnson, Pfizer, and GlaxoSmithKline, could enter this segment to complement their current offerings of general pain relievers and topical analgesics. However, if Icy Hot or Aleve TENS are not solid growth producers, it is likely other companies will forgo the investments to develop new TENS-based pain management devices. If market success is strong for Icy Hot TENS and Aleve Direct Therapy TENS, other marketers may consider entering the space via acquisition of small companies or by licensing technologies necessary to enter this up and coming market. Pfizer, the maker of Advil and Thermacare Heat Wraps, may enter the pain management devices segment.

The market for pain management devices is expected to record strong growth over the next five years, driven by several factors including a growing aging population, popularity of TENS and light-based devices, convergence of multiple technologies in a single device making it effective for multiple types of pain treatment, and the launch of devices that are more comfortable, lightweight, portable, and user friendly. The U.S. market for pain management devices are expected to register positive growth through 2021. Among the powered devices, vibration/massage devices will continue to be the largest category; however, light and TENS devices will register the highest growth through 2021.

In conclusion, the pain management devices market is expected to grow at a rapid pace as these products enjoy wider retail distribution, increased consumer interest and trial, and HCP recommendations. The aging population will also support healthy growth of these devices as the incidence of chronic pain increases. We foresee traditional OTC brands and pain management devices being able to coexist with both segments appealing to various pain management needs of consumers. Additional pharmaceutical companies may enter this market segment; however, licensing agreements or acquisitions of technology will be needed to facilitate market entry by other companies.

Key Pain Management Devices Market Drivers Through 2021



About the IRI/Kline Alliance

Information Resources, Inc. (IRI) the global leader in innovative solutions and services for consumer, retail and over-the-counter healthcare companies, and Kline & Company, a global market research and management consulting firm, have established an exclusive alliance to serve the worldwide, over-the-counter (OTC) drug and overall consumer healthcare industries. This powerful alliance provides a higher level of data accuracy and an unparalleled, global range of thought leadership on stimulating topics in the consumer healthcare space.

As part of this collaborative relationship, IRI contributes its granular, widely recognized, point-of-sale (POS) market data, related insights, and thought leadership. Meanwhile, Kline provides its unmatched historical database, global network, and 360-degree view of the complex OTC drug market, including its comprehensive channel coverage and vast expertise in the area of Rx-to-OTC switches.

The collaborative thought leadership will manifest through white papers like this one on such topics as Rx-to-OTC switch, merger and acquisition activity, new product innovation, as well as trends and issues in international and emerging markets within the OTC drugs industry.

About Kline:

Kline is a worldwide consulting and research firm dedicated to providing the kind of insight and knowledge that helps companies find a clear path to success. The firm has served the management consulting and market research needs of organizations in the agrochemicals, chemicals, materials, energy, life sciences, and consumer products industries for over 50 years. For more information, visit www.KlineGroup.com

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