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The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Tariffs are hitting medical supplies and costs 'will be passed on to the consumer'

Do Your Patient Services Align with Your Commercial Objectives?

Innovation and enable efficient and modern regulatory oversight

Oracle Extra

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

Tariffs are hitting medical supplies and costs 'will be passed on to the consumer'

Adriana Belmonte

Associate Editor

Yahoo Finance Sep, 2019,

Tariffs set to drive up healthcare costs?

[U.S.-China trade tensions](#) continue to escalate as new tariffs took [effect on September 1](#).

Americans are already feeling the effects of these [tit-for-tat taxes](#), particularly farmers who rely on [agricultural exports to China](#). [But it's not just agricultural products that have been getting hit — medical supplies are also feeling pressure](#).

Michael Einhorn, president of Dealmed, a medical supply distributor, predicts that the trade war will drive up the cost of health care even more. This is because many products rely on China for manufacturing.

"People will see an increase," Einhorn said on Yahoo Finance's On the Move. "The margins are very thin on health care supplies. They're very scrutinized ... and ultimately, will be passed on to the consumer."

'Think of products like gauze'

Consumers are already paying for this trade war — [projections](#) have the cost at between \$767 to \$2,294 depending on the size of the household. A recent note from J.P. Morgan puts that [number at \\$1,000 per household](#). [And it's not just consumer items being affected](#).

"Think of products like gauze that are made in Band-Aids," Einhorn said. "Think of other products like medical gloves."

He continued: "These products are used on an everyday basis not only on the professional side such as physician offices, surgery centers, and hospitals, but also on the consumer side — products you'll buy in a pharmacy. And those products will be somewhat affected somewhere between 10% and 25%."

[Our next All Markets Summit is coming up!](#)

'Medical products should not be tariffed at all'

The current U.S. health care system already sees exorbitant costs. U.S. [health care spending](#) grew 3.9% in 2017, [reaching \\$3.5 trillion or \\$10,739 per person, according to the Centers for Medicaid and Medicare Services \(CMS\)](#). [That accounts for about 17.9% of the nation's GDP](#).

"The reality is: costs will go up across the board," Einhorn said. "Not only because of the tariffs, but because what's happening behind the scenes, and [that is] the disruption of the supply chain."

Tariffs on medical supplies could drive up health care costs. (Graphic: David Foster/Yahoo Finance)

Einhorn's solution? Tariff exemptions or waivers.

"A waiver would make a big difference," he said. "There have been requests put in for about 40 different products to be waived that hasn't happened yet in the first round. Some of the subsequent rounds there have been waivers. But as of right now, there haven't been any waivers set to go into effect in September."

The Office of the U.S. Trade Representative (USTR) [released a list](#) of 110 exempted products from tariffs. Only nine of those are types of medical devices.

"Ultimately, medical products should not be tariffed at all," Einhorn said. "That's my opinion. I think there are so many issues outside of the trade war and it's so insecure in terms of the supply chain. I think messing around with it in any form is dangerous with pandemics such as Ebola, which are resurfacing in Africa. You can't risk running out of face

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masks or gloves or exam gowns. Those things ... should be waived entirely.”

Adriana is an associate editor for Yahoo Finance. Follow her on Twitter [@adrianambells](https://twitter.com/adrianambells).

Do Your Patient Services Align With Your Commercial Objectives?

By Dana Edwards, Navigant

After making it through the rigorous processes of product development and regulatory approval, a commercial stage company ideally should know precisely customers’ needs related to access and a strategy to meet those needs. Unfortunately, companies often apply a one-size-fits-all program template because, maybe, for example, it worked in the past or “that’s what our competitors are offering.”

Just as new products require unique journeys from concept through development to gain approval, they also need customized strategies to gain traction once on the market. A successful product commercialization program takes a multifunctional, multichannel approach that adroitly positions the product with stakeholders – patients, providers, and payers – across the care continuum.

As a critical component to this continuum, support services must be designed to attract and benefit the ideal patient and provider targets. Thoughtful consideration and planning must drive patient access and uptake, and mechanisms need to be implemented to evaluate effectiveness. As such, manufacturers should view each new product launch as a unique event, and create a program specific to the drug or device, especially with respect to the patient and provider journeys, as well as relevant regulations.

This article examines how to determine the level of support services required for your new product launch, as well as considerations for setting up those support services compliantly.

Setting the Right Strategy

To begin, make sure your team is creating a commercialization strategy based on current reality, and not assumptions made early in the product development stages. Much can change from early concept to product launch – including the defined market, market development needs, ideal patient pool, competitive landscape, regulations, and more.

For example, an up-and-coming biotech company experienced a massive turnover in product team staff a few months prior to launch. Given the timeline to launch, the new team relied on the assumptions of its predecessors, which completely underestimated the market’s pent-up demand for the technology. This resulted in higher demand for product and services than the company could initially accommodate.

With much at stake, the team quickly regrouped to reset the commercialization strategy and

expand support services. While the product went on to become a best-in-class service offering, the initial launch would have gone much more smoothly if the original assumptions had been reviewed, tested, and validated prior to market launch.

In addition, as you begin investing in developing your pre-launch strategy, assess the market using a mix of qualitative research and real-world evidence from comprehensive claims datasets. This will allow you to translate qualitative insights into the realities of real-world application of the current standard of care, as well as uncover potential barriers to adoption and surmise a defensible estimate of your product’s realizable market value. The results also will inform your market development and commercialization strategies, including appropriate patient services to address potential access barriers.

As you form and populate an appropriate commercialization strategy, focus on three high-level areas:

1st Product type

From manufactured biologics to medical devices with companion diagnostics, the variety of life sciences products entering the market is increasingly complex and may require new services to support patient access. These new products often come to market via intricate routes of administration, alternative use cases, site of care differences, highly specific patient candidate pools, and heightened regulatory requirements that sometimes include a Risk Evaluation and Mitigation Strategies (REMS) program.

Each of these factors will dictate service components that need to be incorporated into the service model and special considerations for service execution. For example, does your product require a physician to administer the product, or is it self-administered? Are there any special monitoring requirements, or does the product require special handling, like cold chain distribution? Does the product have shelf life considerations?

1st Patient journey

The patient journey depends on a variety of factors, including the disease area, standard-of-care treatment modality, and how the product fits into current standard of care. The goal of support services is to help ensure the smoothest, most streamlined patient experience possible — fully considering issues of access, affordability, and adherence during and after the decision is made to prescribe the product:

- Access – Is the patient required to exhaust other treatment options before gaining consideration? Will the patient have to go to a pharmacy to pick up a prescription, visit an academic center of excellence to receive an infusion, undergo a minimally invasive surgical procedure, or something else?
- Affordability – Will insurance cover the cost, or must the patient pay out of pocket? Are there special considerations with your target patient population?
- Adherence – Are there socio-economic, health-system, disease state, or other factors that could impair a patient’s willingness or ability to comply with treatment requirements or follow-up care?

The answers to these questions will help to inform the types of services you consider including in your commercialization strategy.

1st Provider stakeholders

The more conveniently clinicians can get up to speed on the clinical and economic benefits a new product offers, the more likely they are to adopt it. Knowing this — and that most payers, integrated delivery networks, and hospital systems now rely on cross-functional committees to determine which therapy options to adopt — it is critical to incorporate support services that help foster “big picture” understanding of how a product will benefit the healthcare system, while also catering to the prescribing specialty area and expertise level to trigger diagnosis and, if necessary, referral.

For example, if most of your patient population will require treatment from a specialist, but first must present to a primary care physician, then support services should be created to help educate PCPs about the product indications, and, if necessary, referral pathways for patients. Likewise, consider educational services for specialists to understand when to choose your new product over the standard of care, as well as ways to streamline processes, such as through EMR integration and digital prescribing.

Tactical Implementation

After assessing the product type, patient journey, and provider stakeholder needs, your product commercialization strategy can begin to take shape. At this point, begin outlining the tactics to implement as part of your product support service programs, taking into consideration any budgetary needs and/or regulatory requirements or restrictions.

These programs typically provide a range of services that support patient access to therapy, including:

- **Reimbursement support** to help patients navigate their insurance coverage. Reimbursement support includes services like benefit investigations to research a patient’s policy for coverage, prior authorization support to help obtain appropriate authorization for coverage, or appeals support. For this, you need to factor in the reimbursement environment and payer landscape – coding, coverage, and payment considerations for patients to gain access. Also, reimbursement support might range from automated benefit verification or prior authorization for pharmacy benefit to high-touch appeals support for medical benefits. So, what level of support does your program need?
- **Fast Start or Bridge programs** to help patients initiate therapy quickly while working through access challenges.
- **Patient assistance** in the form of free product for uninsured patients, financial assistance or co-pay assistance for underinsured patients, or referrals to

charitable organizations for government-funded insured patients.

- **Adherence support** to help patients initiate and stay on therapy. For this, consider clinical vs. customer service staff vs. automated outreach. For example, will you send patients automated refill reminders, or hire customer service representatives to make personalized follow-ups based on AI generated triggers?

- **REMS support** to meet FDA directed requirements to prevent, monitor, and/or manage a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of such an event. These can range from offering educational packets to full registry tracking, and more.

Also, consider the level of support to provide from low-touch — such as automated technology-based support — to high-touch, full-case management support. For example, for low touch, you might provide general information on whether the product is covered through government-sponsored and/or commercial and private insurance programs. For high touch, you might go a step farther and enable your customer service representatives to call an insurance provider directly on behalf of a patient to determine coverage based on that patient’s specific policy.

As you begin to build out your commercialization plan, consider these common areas of support need:

Customer Access

How will customers initiate and access services? Do you need to set up a provider portal or website? Will a designated phone or fax number be needed? Have you established clear standard operating procedures (SOPs) that must be followed? Does a CRM or database need to be set up to support execution of services and as well as meet reporting requirements?

Staff Training

Internally, you will need to provide operational training on how to administer these services, and clinical training so your customer service representatives understand the product they are supporting. Consider, for example, what your customer service representatives need to know to educate providers and/or help patients. Are there any restrictions on what they can or cannot say or do? Do you need to create any support materials, such as telephone scripts, email templates, FAQs, etc.?

Communication and Marketing Planning

How will you drive patient and provider awareness of your program? What tools does your sales team need? For example, they may need talking points to help them explain the program, or “do’s and don’ts” guidance. Maybe they need promotional materials, such as brochures, an overview video, or product samples?

Too often, this area becomes a classic case of the left hand not knowing what the right hand is doing. Often, these programs are set up to provide a certain type or level of service. Make sure your sales team fully understands the program nuances and what support services it entails.

For example, in one recent case, a field team member erroneously promised a clinician help writing an appeal letter for reimbursement. However, the program SOPs dictated that the program could only provide a template with demographic information filled in – the clinician must write his or her own clinical rationale for why coverage should be allowed. Upon learning this, the field team member was forced to backtrack and reset expectations, which angered and frustrated the physicians, who were then less enthusiastic about the prescribing the new product.

The better your entire team understands what the program offers — and how to access resources if any questions arise — the more successful your product commercialization strategy can be.

Compliance Concerns

Are you familiar with recent regulations in the patient services space? What hurdles to access are you anticipating and what assistance can be provided to address these compliantly?

Support service programs are under vigilant compliance scrutiny; field force monitoring, transparency reporting, and risk-assessment activities are critical when launching a medical device or pharmaceutical product, as is having a plan for the ongoing administration and monitoring of your service offering. It also is important to ensure your patient services programs are administered in a compliant manner, including compliant systems, written standards, adequate training of personnel, and with appropriate monitoring.

Successful product commercialization strategies find a strong balance among meeting regulatory expectations and patient and provider needs. There is no one-size-fits-all approach for an industry or therapeutic area. As such, adequate resources – including time, staff, and budget – should be allocated and based on the product, patient journey, and potential realizable market. Manufacturers that invest these necessary resources go to market confident their commercialization strategies and support service plans will be best equipped to succeed.

About The Author

Dana Edwards is a director in [Life Sciences at Navigant](#). With more than 20 years of experience in the pharmaceutical and life science industry, she helps pharmaceutical and biotech manufacturers identify solutions to support patient access to therapy. She has led the design, development, and implementation of programs servicing both patients and providers to support patient access to and coverage for high-cost therapies. Her focus on quality assurance and process improvement has led to innovative work processes and system solutions to facilitate a portfolio of services addressing complex reimbursement issues across payer types.

Statement on new steps to advance digital health policies that encourage

Innovation and enable efficient and modern regulatory oversight

For Immediate Release:

September 26, 2019

Statement From:

*Principal Deputy Commissioner - Office of the Commissioner
Amy Abernethy MD, PhD.*

Today, the U.S. Food and Drug Administration released a suite of guidances to continue to encourage innovative approaches to the development of digital health tools, and to ensure the agency's approach to overseeing these technologies advances along with it.

Patients, their families and their health care professionals are increasingly embracing digital health technologies to inform everyday decisions, from tools that more easily report blood glucose levels to smart watches that can detect atrial fibrillation. These tools provide patients with a wealth of easily-accessible information that can help them make better and more efficient decisions, take steps to improve their lifestyles and health choices, and experience better outcomes.

We believe that an appropriate regulatory framework that takes into account the realities of how technology advances plays a crucial role in the efficient development of digital health technologies. We've maintained, since we issued our [Digital Health Innovation Action Plan](#) in 2017, that our approach to regulating these novel, swiftly evolving products must foster, not inhibit, innovation.

Our plan outlined our efforts to reimagine the FDA's approach to ensure all Americans have timely access to high-quality, safe and effective digital health products. As part of this plan, we've accomplished several key initiatives, including [launching](#) and [testing the digital health software precertification pilot program \("Pre-Cert"\)](#) and [taking steps to modernize our policies](#).

The guidances issued today continue those efforts announced as part of the Digital Health Innovation Action Plan and address key provisions of the [21st Century Cures Act](#), that offer additional clarity about where the FDA sees its role in advancing safe and effective digital health technologies. We've taken the goals we were entrusted with by Congress under the Cures Act and are building on these provisions to make sure that we're adopting the full spirit of the intent to provide a practical oversight framework that is risk based.

The first guidance we're announcing, [Clinical Decision Support Software](#), is a revised draft guidance based on careful review of public comments received on the previous draft published in 2017.

We recognize that software that provides clinical decision support (CDS) has many uses, including helping providers, and ultimately patients, identify the most appropriate treatment plan for their disease or condition. An example of CDS could be software that analyzes family history, electronic health record data, prescription patterns and geographical data in order to help health care professionals

identify patients who may be at risk for opioid addiction. These types of software programs are intended to inform the physician's clinical management of their patient. This technology has enormous potential to improve clinical decision making. We want to encourage developers to create, adapt and expand the functionalities of their software to support providers in diagnosing and treating diseases, while also ensuring the software doesn't introduce unacceptable risk to the patient.

After first publishing the draft guidance in 2017, the agency received feedback from many stakeholders advising us on improvements that could be made to better clarify the agency's oversight of CDS products. We heard you and worked to incorporate that important feedback. More specifically, stakeholders asked that the FDA consider the inclusion of risk-based categorization of software products based on the risk to patients if a software product malfunctions, so we've leveraged the [International Medical Device Regulators Forum External Link Disclaimer \(IMDRF\) risk-based framework for categorizing products. The IMDRF final document, "Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations External Link Disclaimer," progressing from our international harmonization efforts, establishes common principles that can be used by all stakeholders, including regulators, to promote safe innovation and protect patient safety. The draft guidance clarifies categories of CDS that would be subject to FDA oversight, categories of CDS for which we intend not to enforce applicable regulatory requirements \(known as enforcement discretion\) due to the software's low risk to patients, and CDS categories that do not meet the definition of a medical device.](#)

In this draft guidance, we propose to focus our regulatory oversight on CDS functions that are intended to help health care professionals and patients inform their clinical management for serious or critical conditions and that are not intended for health care professionals to independently evaluate the basis of the software's recommendations. An example of a product we would focus our oversight on would be CDS that identifies hospitalized, type 1 diabetic patients at increased risk of postoperative cardiovascular events and which does not explain why the software made that identification to the health care professional. In this case, if the CDS provides information that is not accurate (e.g., inappropriately identifies a patient as low risk when he is high risk), then any misidentification could lead to inappropriate treatment and patient harm. Since the potential for patient harm is significant, FDA regulation plays an important role in evaluating the software's safety and effectiveness.

We believe our proposed approach for regulating CDS not only fulfills the provisions of the Cures Act, but also strikes the right balance between

ensuring patient safety and promoting innovation by clarifying which products would be the focus of FDA's oversight and which would not.

Also issued today was the final guidance [Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act](#) which addresses other digital health provisions included in the Cures Act. Specifically, this final guidance outlines the FDA's interpretation of the types of software that are no longer considered medical devices under the amended definition of device. We're making clear that certain digital health technologies – such as mobile apps that are intended only for maintaining or encouraging a healthy lifestyle – generally fall outside the scope of the FDA's regulation. Such technologies tend to pose a low risk to patients, but can provide great value to consumers and the healthcare system.

The digital health technologies described in this guidance (3060) have been previously discussed in existing medical software guidances. That's why today we are also updating four previously issued FDA final guidances to align with interpretations and policies under the Cures Act: [Final Guidance on Policy for Device Software Functions and Mobile Medical Applications](#); [Final Guidance on General Wellness: Policy for Low Risk Devices](#); [Final Guidance on Off-The-Shelf Software Use in Medical Devices](#); [Final Guidance on Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices](#). [Changes to these documents include clarification that many products previously under enforcement discretion no longer are medical devices under the 21st Century Cures Act, and therefore are not subject to FDA's regulations and oversight.](#)

Overall, these important guidance documents being issued today expand on our efforts to both encourage innovation in the ever-changing field of digital health and protect the public health. Our aim is to provide more clarity on our risk-based approach to digital health products, and, in particular, to provide more detail on those technologies and applications that would no longer be classified as a medical device subject to FDA regulation according to the Cures Act. These documents are critical elements of FDA's comprehensive approach to digital health. We are committed to promoting beneficial innovation in this space while providing appropriate oversight where it's merited.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Continue on to next page, a Oracle extra.

Oracle Extra for October 2019

The FDA's Center for Devices and Radiological Health (CDRH) hosts webinars and calls to educate stakeholders on guidances and other topics related to the regulation of medical devices and radiation-emitting products. These forums provide the medical device industry and others with the chance to interact with FDA officials and have their questions answered.

This page provides information on upcoming and past webinars and calls held by CDRH. Additional industry education is provided on [CDRH Learn](#).

Upcoming Webinars:

[Webinar - Dental Devices Premarket Submissions - October 2, 2019](#)

[Webinar - Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Pre-market Approvals, De Novo Classifications, and Humanitarian Device Exemptions – Final Guidance - October 16, 2019](#)

[Webinar - Humanitarian Device Exemption Program - October 21, 2019](#)

[Webinar - Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program: Draft Guidance - October 28, 2019](#)

[Webinar: Collaborative Communities - October 29, 2019](#)

[Webinar - The Special 510\(k\) Program: Final Guidance - October 31, 2019](#)

[Webinar - Safer Technologies Program: Draft Guidance - November 6, 2019](#)

[Webinar - Safety and Performance Based Pathway Performance Criteria - November 7, 2019](#)