Life & Health

Medical Device Communiqué

Q4 2013

WHAT DOES THE MED TECH INDUSTRY FACE GLOBALLY?

Global Medical Device companies – or companies that want to go global – aren't operating in a gentle environment. A recent research survey of 125 industry executives representing 89 companies across 16 countries shows just how difficult the challenges are. The survey, conducted by Axendia, Inc., has produced a report whose title sets the tone: "Walking the Global Tightrope: Balancing the Risks and Rewards of Med-Tech Globalization."

There's good and challenging news in the responses of industry executives. On the good news side, nine of ten expect very strong growth over the next three years, with emerging economies representing rapidly growing marketplaces. In fact, 88% expect

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WHAT DOES THE MED TECH INDUSTRY FACE GLOBALLY? *(Continued)*

increased sales in emerging markets. Even in developed markets, the prospects look good with 69% of respondents expecting increased sales. The not-surprising challenges center on risk, with seven of ten respondents reporting moderate to high risk based on their level of visibility into critical suppliers, according to information released by Axendia.

Here are some of the most significant findings about what makes industry execs worry:

- 65% view the global regulatory environment as the top business threat over the next three years;
- 59% worry about maintaining consistent quality standards across internal and external sites;
- 90% would like access to real-time data and on-demand data from critical suppliers, contract manufacturers and other Tier 1 suppliers;
- 60% worry about the quality of products, raw materials or services provided.

Med tech companies aren't going to pull back on their global plans. There's too much opportunity for growth. Notwithstanding that opportunity, the survey identifies the three issues that executives point to as being of greatest concern: the increasing complexity and cost of complying with global regulations; ensuring the quality of finished products and raw materials around the globe; and maintaining consistent standards across an extended network of internal and external sites.

CHANGES AT FDA AND CDRH

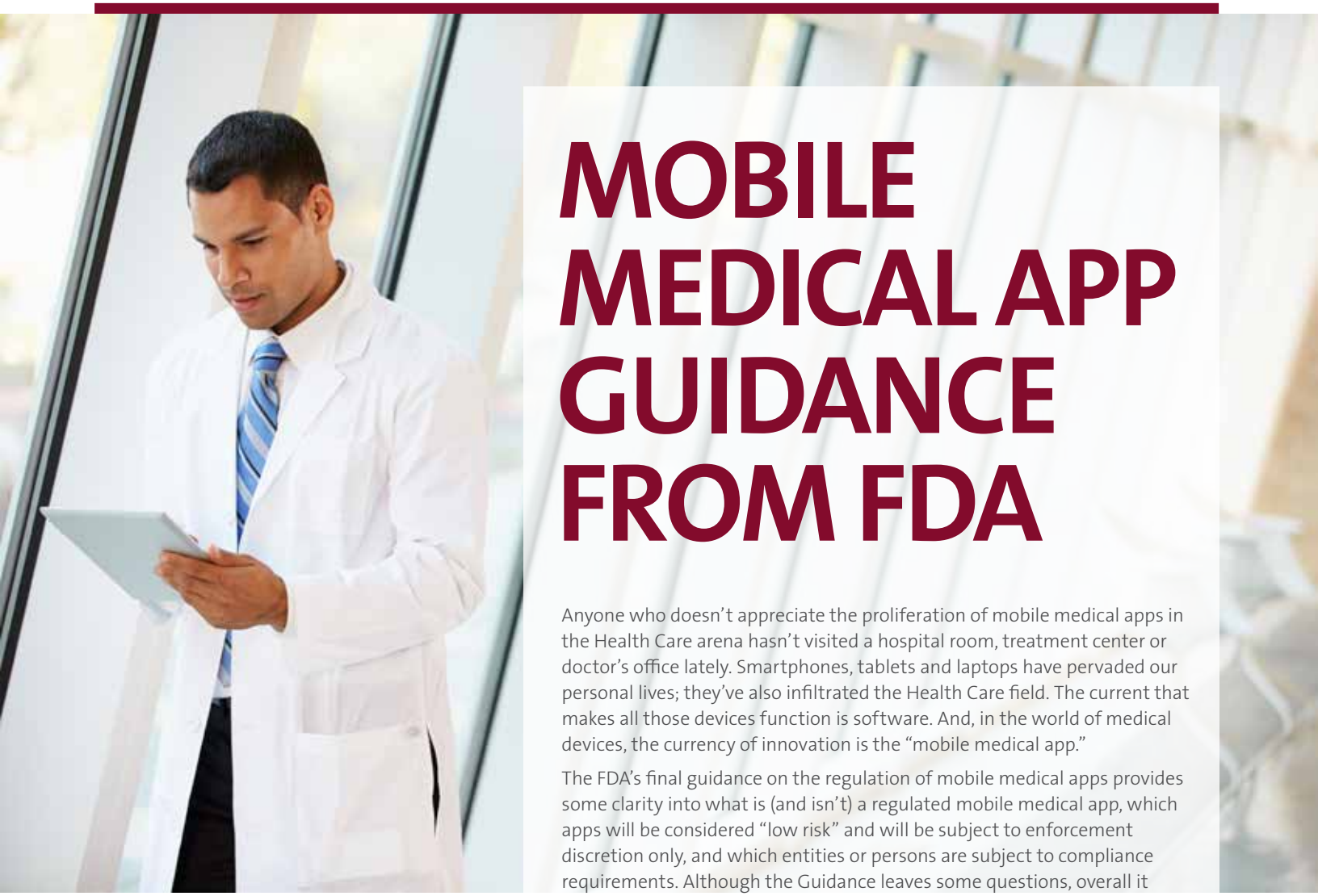
The structure of FDA and CDRH isn't working for the mission facing it. At least, it isn't working as well as it needs to. That was the message from FDA Commissioner Margaret Hamburg, in a memo sent to senior leaders at FDA. The memo, reprinted in a in Forbes Magazine September 8th article, *Did FDA Just Announce a Major Reorganization?*, sets the backdrop: increasing complexity of the products it regulates, rapid strides in scientific innovation, the globalization of the medical supply chain and expanded authorities given to the FDA through new legislation. Those factors, writes Hamburg, "... require the Agency to continue to find ways to ensure that we are meeting our critical public health and regulatory mission."

Hamburg has set up a Program Alignment Group of senior FDA leaders and charged them with identifying and developing plans to modify FDA's functions. In particular, according to a Hamburg memo, "...it is imperative that there be greater clarity and transparency about relative roles and responsibilities of the Directorates, ORA, and the Centers, as well as greater operational and program alignment among these organizations that avoids duplication of function and effort..." Hamburg continues, "More specifically, we need to transition to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, well-designed and coordinated implementation, and a de-layered management structure."

Hamburg didn't set a schedule for the Program Alignment Group's work, but over in the Center for Devices and Radiological Health's Office of Compliance already changes set to become effective in November. The CDRH's changes echo Hamburg's emphasis on a "function-based structure" rather than a "product-based structure." Here's what some of the reorganization will look like, according to an update by the law firm Covington & Burling LLP:

- Two new divisions will replace the Divisions of Enforcement (A and B). Replacing them will be two new Divisions that highlight the CDRH's evolving strategic focus. The new Division for Premarket and Labeling Compliance will focus on manufacturers' compliance with premarket approval and clearance, advertising, promotion and labeling requirements. The new Division of Manufacturing Quality will develop policy on quality issues, review domestic inspections and classify recalls.
- A new Division of International Compliance Operations will supervise the FDA's increasingly global footprint and will have overseas manufacturing quality functions.
- The Division of Risk Management Operations will be renamed the Division of Analysis and Program Operations but will be largely unchanged otherwise. The current Division of Bioresearch Monitoring will stay as it is.

It's hard to anticipate how the CDRH restructuring might be affected by the larger FDA reorganization. The CDRH's changes are set to become effective this year and show a clear emphasis on promotional activities, which has lagged significantly behind the oversight of promotional and advertising attention on the Pharmaceutical side of the FDA.



MOBILE MEDICAL APP GUIDANCE FROM FDA

Anyone who doesn't appreciate the proliferation of mobile medical apps in the Health Care arena hasn't visited a hospital room, treatment center or doctor's office lately. Smartphones, tablets and laptops have pervaded our personal lives; they've also infiltrated the Health Care field. The current that makes all those devices function is software. And, in the world of medical devices, the currency of innovation is the "mobile medical app."

The FDA's final guidance on the regulation of mobile medical apps provides some clarity into what is (and isn't) a regulated mobile medical app, which apps will be considered "low risk" and will be subject to enforcement discretion only, and which entities or persons are subject to compliance requirements. Although the Guidance leaves some questions, overall it reinforces the risk-based approach the FDA has adopted in recent years.

The FDA defines mobile medical apps as "... software programs that run on smartphones and other mobile communication devices. They can also be accessories that attach to a smartphone or other mobile communication device, or a combination of accessories and software." Instead of attempting to develop an across-the-board set of regulations that covers all apps used in the Health Care industry, the FDA is taking a "tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of device and that are intended to be used as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device." FDA regulates those apps it considers to be high-risk. For those apps it considers to pose minimal risk to patients, the FDA will exercise "enforcement discretion" and "...will not expect manufacturers to submit premarket review applications or to register and list their apps with the FDA."

The Agency has considerately provided examples of medical mobile devices it regulates, those for which it will apply enforcement discretion, and exactly which entities or persons are subject to the new requirements.

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MOBILE MEDICAL APP GUIDANCE FROM FDA *(Continued)*

FDA-Regulated Mobile Apps

Regulated apps use a mobile platform's built-in features such as light, vibrations, camera or other similar sources to perform medical device functions (e.g., apps used by licensed practitioners to diagnose or treat disease). Here are examples of the functions that regulated apps perform:

- Measure and display electrical signals produced by the heart (electrocardiograph or ECG)
- Amplify and project sounds associated with the heart, arteries and veins, and other internal organs (such as an electronic stethoscope)
- Measure physiological parameters during cardiopulmonary resuscitation (CPR)
- Record, view or analyze eye movements to diagnose balance disorders
- Produce controlled levels of test tones and signals for use in conducting diagnostic hearing evaluations in the diagnosis of possible otologic disorders
- Measure the degree of tremor caused by certain diseases
- Measure blood oxygen saturation
- Measure blood glucose levels
- Alter the function or settings of an infusion pump
- Control or synchronize computed tomography or X-ray machines
- Control or change settings of implantable neuromuscular stimulator
- Control the inflation or deflation of blood pressure cuffs
- Connect, display or transfer medical device information as part of a patient monitoring system

Mobile Apps Subject to Enforcement Discretion

The FDA intends to exercise enforcement discretion on a number of apps that may qualify as medical devices, because these apps pose lower risk to the patient. Many of these apps are used to educate, monitor or track patient status. Examples include apps that alert asthmatics of environmental conditions that may cause symptoms, prompt users to manually enter symptomatic or behavioral information pre-defined by a healthcare provider, use patient characteristics to provide patient-specific screening and preventive recommendations, record clinical conversations between practitioners and patients, react and send an alert or general emergency notification to first responders, and keep track of medications and provide reminders to patients for improved medication adherence.

What is a "Manufacturer?"

Knowing who is regulated is as important as knowing what is regulated. The FDA defines a mobile medical app manufacturer as "any entity or person who initiates or develops specifications for mobile medical apps, or who creates, designs, labels, re-labels, or modifies a mobile medical app." Under the Guidance, manufacturers are subject to regulatory app requirements including Quality System Regulations. Alternately, manufacturers of mobile platforms, such as smartphones, who "solely distribute or market their platforms and do not intend the platform (by marketing claims such as labeling claims or advertising material) to be used for medical device functions will not be subject to regulation as device manufacturers. This marketing-related exemption should trigger some bells of caution for Medical Device manufacturers: remember that the CDRH has reorganized its organizational structure to increase its focus on promotional, marketing and labeling issues.

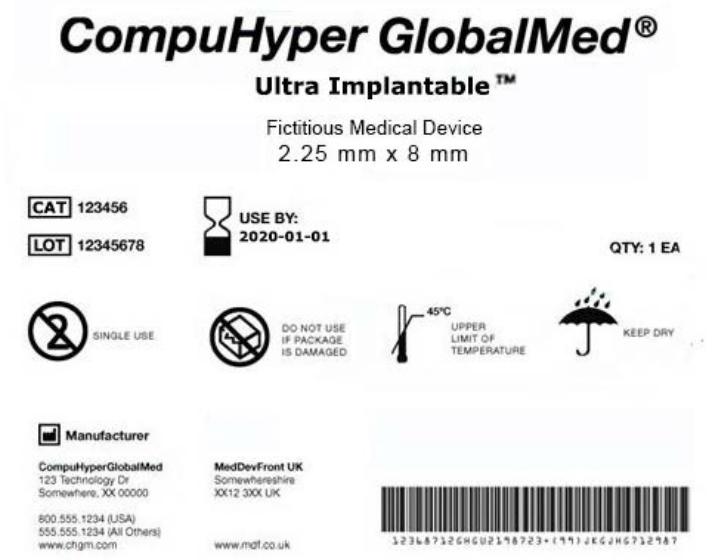
THE FINAL UDI RULE

The Medical Device industry knew it was coming and even contributed to its formulation. Well, now the FDA's Unique Device Identifier (UDI) Final Rule is here. And, standing shoulder to shoulder with it is the FDA-administered Global Unique Device Identification Database (GUDID), a publicly searchable database that will serve as a reference catalogue for every device with an identifier. Reflecting the FDA's risk-based approach, the Agency plans to phase in the UDI system, beginning with high-risk medical devices. Once fully implemented, the system is designed to quickly and efficiently identify marketed devices when recalled, improve the accuracy and specificity of adverse event reports, provide a foundation for a secure global distribution chain, and assist in documenting device use in electronic health records and clinical information systems.

The Final Rule is the end result of considerable industry input. In general, high-risk medical devices (Class III) will have to carry unique device identifiers. The FDA defines a UDI as a "... unique numeric or alphanumeric code that consists of two parts:

- A device identifier – a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- A production identifier – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: the lot or batch number within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured; and the distinct identification code for a human cell, tissue or cellular and tissue-based product regulated as a device."

Just as important as the identifier requirements is the FDA's creation of a Global Unique Device Identification Database, which will include a standard set of basic identifying elements for each device with a UDI. Most of the information will be available to the public so users can easily look up information about the device. The FDA has released the Global Unique Device Identification Database Draft Guidance for Industry to provide an overview of the program. As with the UDI program, the FDA is soliciting comments on the draft guidance before it begins work on the final version. Submit electronic or written comments by November 25, 2013.



Fictitious example of what a unique device identifier (UDI) would look like on a medical device label. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, bar code and details about the item.

Source: fda.gov

UL EDUNEERING BRINGS BACK NEWS FROM COMMISSIONER HAMBURG

AdvaMed's Conference in Washington this past September featured a number of impressive speakers and roundtable participants. One of the most important for our industry was FDA Commissioner Margaret Hamburg who spoke at the Conference, offering insight into the FDA's perspective and plans moving forward.

Hamburg praised the increasingly close relationship between the FDA and AdvaMed, noting that the relationship has strengthened as it has matured. One of the outgrowths of that relationship has been "predictable and smart regulations." Hamburg pointed to two recent events that demonstrate those smart regulations:

1. The final UDI rule that was in development for several years, relied heavily on input from Medical Device companies and organizations.
2. The Mobile Medical Apps Guidance, under which the FDA had already approved 75 apps.

Both rule and guidance help to provide clarity to the industry and to demonstrate the risk-based, smart-regulation approach the FDA has embraced. Beyond the two regulatory efforts, Hamburg noted some procedural and legislative actions that are making their marks on the industry.

The major legislative factor is FDASIA, which enables products to get to patients more quickly through dedicated funding and improved performance goals. The end result for the industry is greater efficiency, continuity and predictability. Those goals are increasingly within grasp, despite the CDRH's historic underfunding compared to other centers and, more recently, the elimination of $409 million from the FDA's budget due to sequestration. Those cuts, said Hamburg, make it difficult to speed the pathway to market for medical devices.

Despite the budget cuts and the increasingly challenging approval process created by the escalating complexity of medical device products, Hamburg emphasized the FDA's ability to meet many of its performance goals and her confidence that the Agency's approach to risk-based, smart regulations along with a collaborative relationship with the Medical Device industry would produce results that benefit both the industry and the patient population.

About UL EduNeering

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