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IN THIS ISSUE

Industry Sings Praises of Obama's Choice to Head FDA

Representatives from the medical device community are applauding President Barack Obama's decision to nominate Robert Califf to be the next commissioner of the FDA.

"As one of the nation's preeminent cardiologists, Dr. Califf understands the value medical technology brings to improving patient outcomes, and we look forward to working with him to ensure that American patients have timely access to the life-saving and life-enhancing innovations our industry provides," says Steve Ubl, AdvaMed president and CEO, in an emailed statement to *IDDM*.

"As a long-time collaborative partner with the FDA on initiatives to promote the safe and effective use of medical imaging equipment, we look forward to ongoing cooperative efforts with the agency and

(See **Califf**, *Page 2)*

Medtronic Allowed to Resume Swedish Sales of Insulin Pump

A Swedish court has put temporary brakes on an order from the country's Medical Products Agency that would require Medtronic to halt sales and recall its MiniMed 640G insulin pump. The stay will remain in place as Medtronic appeals the regulator's actions before another court.

The decision by the Administrative Court of Appeal in Stockholm comes about two months after the company informed patients, healthcare providers and regulators in several EU countries and Australia there was an issue with the Minimed 640G pumps that affected the bolus screen. The screen would not always time out, possibly creating confusion by showing an older, inaccurate bolus amount.

Medtronic did not remove the pump from the market, but sent a notice to users and healthcare professionals with updated and clarified

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Califf, *from Page 1*

Dr. Califf if he is confirmed," adds Patrick Hope, executive director of the Medical Imaging & Technology Alliance.

To some, Califf always has been the obvious choice to head the agency. "When asked who was on my short list of potential commissioners, I said 'Robert Califf is the short list,'" Peter Pitts, president and founder of the Center for Medicine in the Public Interest and a former FDA associate commissioner, tells *IDDM*.

Steve Niedelman, a former FDA official who now consults medical device companies, seconds that assessment, noting that Califf was a contender six years ago when Margaret Hamburg was nominated.

Not everyone has voiced support for Califf's nomination, however. Michael Carome, director of Public Citizen's Health Research Group, has urged the Senate to reject his nomination, citing Califf's long history of financial ties to industry. "His nomination undoubtedly comes as welcome news to the pharmaceutical and medical device manufacturers, but is bad news for patients and public health," Carome says in a statement.

Margaret Anderson, executive director of FasterCures and past president of Alliance for a Stronger FDA, is one of many who disagree with this assessment, telling *IDDM* that early in his tenure as deputy commissioner at the FDA, Califf spoke out about the science of patient input and related methodologies in clinical trials, a key focus of the 21st Century Cures Act.

Robert Harrington, chairman of the Department of Medicine at Stanford University, worked with Califf at Duke University for more than a decade, and says the nominee understands both the appropriateness of industry-academic collaborations and the necessary boundaries. By necessity, Califf has collaborated with research funders, including private industry, to plan and implement clinical trials, he says.

Pitts says Califf's experience as deputy commissioner and his past dealings with FDA employees have earned the respect of senior agency staff.

If the Senate approves his nomination, Califf will come into his role as the agency is facing a number of challenges, including recruiting and retaining staff and assuming new responsibilities if the 21st Century Cures Act goes into effect. — Kellen Owings

Medtronic, IBM Watson Join Forces With Israel VCs for Digital Health

A partnership of four organizations that includes medtech giant Medtronic has been awarded a tender for a life sciences incubator in Haifa, Israel, with the aim of advancing digital medicine.

IBM Watson Tech, Pitango Venture Capital and Rambam MedTech make up the rest of the team that will establish the incubator, which will focus on, among other areas, telemedicine, wearable and implantable diagnostic sensors, advanced diagnostics, personalized medicine and medical devices that interact with the web.

"Digital medicine heralds a revolution in how people will receive medical services.

"We face a number of commercial and technological challenges, which demand complex integration of different disciplines," says Dan Schwartzman, director of the new incubator, in a Rambam statement.

The incubator will be in a new Life Sciences Park that will include five buildings, with the main center scheduled for completion at the end of the year.

The tender is part of a fourth round of competitive procedures for selecting franchisees for an incubator to benefit the northern part of the country, according to a statement from Israel's Ministry of Economy.

The incubator is part of a program administered by the Office of the Chief Scientist within Israel's Ministry of Economy. Established in 1991, the goal of the Technological Incubators Program is to develop ideas into viable startup companies that can raise money from private investors.

Currently, there are 20 incubators in Israel. — Elizabeth Hollis

Nonprofit Questions Effectiveness Of St. Jude Medical's CardioMEMS

A draft report from a nonprofit that focuses on cost-effectiveness in healthcare takes aim at St. Jude Medical's CardioMEMS HF System, saying there is insufficient evidence indicating that the device represents a marked improvement over existing technologies.

That was the conclusion of an analysis from the Institute for Clinical and Economic Review, which also found that with a list price of $17,750, CardioMEMS could impose excessive costs on the overall healthcare system. That figure represents the cost of the device itself and not implantation and monitoring.

Indeed, the institute says the device can be priced much lower. "When estimated patterns of CardioMEMS uptake are considered, our value-based price benchmark for CardioMEMS comes in at $7,622, a nearly 60 percent discount off the current list price," says Steven Pearson, founder and president of ICER, in a prepared statement.

A Breakthrough?

The system is intended for patients with congestive heart failure, a condition that hasn't seen a major breakthrough treatment in more than a decade, according to the draft document. Currently, about 6 million patients are affected by CHF in the U.S., and the costs for treating the condition are expected to rise.

CardioMEMS is a permanently implanted wireless sensor that measures pulmonary artery pressure, which some studies have shown rises before the signs and symptoms of worsening heart failure. Using the sensor, patients may wirelessly transmit data to a secure online database, that allows treating physicians to access this information. St. Jude acquired the system through its 2014 acquisition of Atlanta-based CardioMEMS.

Despite some reservations, the FDA approved CardioMEMS May 28, 2014. It required the company to conduct two postmarket studies as a condition of the approval — one to assess the device's safety and effectiveness with a sample size to detect gender differences, and the other to compare post market effectiveness to a subset of premarket recipients.

ICER remains skeptical, even with the FDA's required studies. "We believe there is a reasonable chance that CardioMEMS would not confer incremental benefit in all subsequent studies or settings," it says in the draft document. It therefore gives the current body of evidence backing the device an "I" rating for inefficient.

ICER also takes aim at the annual budgetary impact of CardioMEMS utilization, which it calculates to be $1.6 billion annually — well above the organization's $603 million per year device budgetary impact threshold.

Company Reacts

St. Jude spokeswoman Kate Stoltenberg tells *IDDM* that the company is confident about the system's value and benefits, adding that many physicians in California and around the country say it represents a significant breakthrough.

"[The] draft report encourages review and comments from the public, including real-world experience from leading clinicians whose experience with the technology has been favorable and supports outcomes realized through the CHAMPION randomized, controlled and comparative clinical trial," she says.

ICER is encouraging public comment on the draft document through Sept. 25, ahead of an Oct. 29 meeting of its California Technology Assessment Forum in Oakland, Calif. That body develops recommendations aimed to improve the quality and value of healthcare. During that meeting, CTAF members will discuss the evidence presented in a revised version of the report and vote on the effectiveness and value of these interventions.

The draft document is available here: www.fdanews.com/092115-St-jude-cardiomems.pdf.
— Elizabeth Hollis

Medtronic-Sweden, *from Page 1*

instructions on how to avoid the problem. It also included an educational piece with all shipments of the device.

A notice posted at the MPA website from the company indicated customers would receive an updated manual in August. However, on July 30, the MPA ordered Medtronic to stop sales of the product and instruct users not to use the Bolus Wizard feature or recall the device. It based its decision on an assessment that the product's software has flaws.

An MPA spokesperson tells *IDDM* that the regulator does not consider the risk for user harm is mitigated and eliminated as much as possible.

Medtronic appealed the regulator's decision. The Stockholm court took up the question of whether sales should continue, hearing a risk assessment provided by Medtronic and written response from Swedish medical experts.

The Stockholm court decided for Medtronic, basing its opinion on the experts' testimony. They provided a statement to the court questioning the regulator's decision.

The group said there is a greater risk of withdrawing the devices, and that there is a group of patients in Sweden that benefits from having a feature on the pump that prevents too low blood sugar levels.

A different court is listening to Medtronic's appeal of the MPA's decision to permanently halt sales. The MPA spokesperson adds that the regulator cannot comment further due to the ongoing litigation.

With the resumption of sales, the Swedish regulator urges patients and healthcare staff to read the pump's product manual.

It also advises healthcare providers to alert Medtronic of any problems associated with the product's use. — Elizabeth Hollis

FDA Hits Troy for Process Validation, Supplier Qualification Sloppiness

Quality system lapses — including process validation snafus — failure to address nonconforming products and not evaluating suppliers efficiently are some of the reasons contract device manufacturer Troy Innovative Instruments has fallen afoul of the FDA.

During a June 5 to 30 inspection of Troy's Middlefield, Ohio, plant, an FDA inspector observed at least six examples in which the firm, which manufactures implantable orthopedic devices, including trocars, lumbar bone screws, rods, nuts and plates, failed to validate a process, according to a Sept. 1 warning letter.

For example, validation studies for a laser etching process that engraves lot numbers on implantables did not include whether the method could result in post-processing metal fatigue.

Also, validation studies for a nitric passivation process did not test for the worst-case scenario for load size.

In addition, the firm failed to test for the worst-case scenario during electropolishing validation studies.

Validation studies for certain welding processes did not include strength testing of the welds.

The FDA also cited the firm for not determining whether adverse events resulted from reworked products.

The warning letter says the firm did not establish procedures to control products that don't conform to specifications, and it failed to document in-process inspections and verification activities.

For example, not all nonconforming products were documented, and data are not being captured for potential corrective and preventive actions, an FDA Form 483 notes.

In addition, the quality manager told the FDA inspector that only out-of-specification results are documented, and so all acceptance activities during the manufacturing process are not being recorded, the 483 says.

Finally, the warning letter dings the firm for failing to ensure that all suppliers conform to specified requirements.

"You are not evaluating and monitoring suppliers on their ability to meet requirements, including quality requirements," the letter says, noting that suppliers are approved and continue to be used without a review of whether their processes are acceptable.

The FDA inspector noted that the company didn't include a risk-based approach to its annual evaluation, since suppliers listed as critical are reviewed or monitored.

Moreover, the firm's annual review of suppliers only rates suppliers on their late deliveries, dollars rejected and responsiveness to corrective actions.

The FDA says it received a response dated July 14 to the Form 483, but the agency could not determine its adequacy.

Outside Help

It has asked Troy to hire an outside consultant to conduct an audit of the firm's manufacturing and quality assurance systems.

"You should also submit a copy of the consultant's report, and certification by your establishment's Chief Executive Officer (if other than yourself) that he or she has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report," the warning letter states.

It requested the consultant to certify the audit by March 1, 2016, and also required a subsequent certification one year later.

The firm did not comment by deadline.

Read the warning letter here: www.fdanews.com/09-21-15-troywarning.pdf, and the Form 483 here: www.fdanews.com/09-21-15-troy483.pdf. — Tamra Sami

SEC Wins $30M from Traders Involved in Hacking Scheme

A Ukrainian national and his company have agreed to pay $30 million to settle with the U.S. government over civil charges of illegally profiting from stolen statements in a case that involved at least two devicemakers.

Last month, the U.S. Securities and Exchange Commission accused more than 30 defendants – individuals and corporate entities, many with Ukrainian ties – of using stolen nonpublic information for illegal profit.

The commission's complaint alleges that over a five-year period, two hackers broke into the networks of Marketwired, PR Newswire Association and Business Wire to steal press releases detailing companies' quarterly and annual earnings data before they appeared online (*IDDM*, Aug. 14). The hackers then sold the releases to traders, including Jaspen Capital Partners and its CEO Andriy Supranonok, who used the information to their financial advantage. Supranonok and Jaspen have now agreed to settle without admitting to allegations in the complaint.

Among the targeted companies were Edwards Life Sciences and San Jose, Calif.-based Align Technology, which markets the Invisalign clear braces system. According to the complaint, the defendants profited from stolen earnings releases from both companies. Assets from those thefts were deposited in accounts frozen by the court.

"Today's settlement demonstrates that even those beyond our borders who trade on stolen nonpublic information and use complex instruments in an attempt to avoid detection will ultimately be caught," says Andrew J. Ceresney, director of the SEC's Enforcement Division, in a prepared statement.

The SEC filed its complaint in the U.S. District Court for the District of New Jersey. Its litigation against the other defendants remains pending. — Elizabeth Hollis

Dentsply to Buy Sirona In Deal Valued at $5.5B

In what they call "a merger of equals," York, Pa.-based dental equipment maker Dentsply has entered an agreement to buy Sirona in an all-stock deal valued at roughly $5.5 billion.

The merged companies are projected to have net revenues of approximately $3.8 billion and about 15,000 employees, according to a prepared statement. Dentsply manufactures and distributes dental and other consumable healthcare products, while Long Island, N.Y.-based Sirona makes dental products, such as CAD/CAM restoration systems.

The combined company will be known as Dentsply/Sirona, with global headquarters in York and international headquarters in Salzburg, Austria, home to Sirona's sales and marketing hub. Sirona's President and CEO Jeffrey Slovin will serve as chief executive of the merged companies, while Bret Wise, chairman and CEO of Dentsply, has been tapped as executive chairman.

During a conference call, executives were asked why Dentsply decided to enter this deal more than a decade after exiting the dental equipment business. Wise explained that previously, Dentsply was in a niche area, and this deal will expand its reach.

"What we're doing today is we're combining the strongest player in dental technologies and dental equipment with the strongest player in dental consumables, and it's clear that the market is trending toward increased use of integrated systems, digital technologies and consumables that can do more when combined with equipment," he explained.

The transaction is expected to close in the first quarter of 2016.

Moody's Investors Service rated the deal credit positive.

The deal comes weeks after the release of a report that found that full-year M&A activity in the medical device arena could exceed $100 billion for the first time, particularly with close of megadeals, such as Medtronic/Covidien (*IDDM*, Aug. 28). During the first half of the year, the total value of closed medtech mergers came in at $83 billion, according to the report from EP Vantage. — Elizabeth Hollis

Sales of Unapproved Device Lands Couple in Hot Water

A couple has pleaded guilty in a California court to charges related to the sale of an unapproved device that they said could be used as treatment for a range of conditions, including AIDS, worms and cancer.

David and Sandra Perez marketed the Energy Wave over the Internet — an unapproved device that consists of a microcurrent frequency generator, two stainless steel cylinders, two personal application plates and a list of auto codes associated with specific disease conditions, according to court documents.

"Users were provided with an operating manual and a listing of 'Auto Codes' that set forth hundreds of digital settings for the device, directed to specific conditions such as abdominal pain, AIDS, diabetes, stroke, ulcer and worms," according to court documents filed in the U.S District Court for the Southern District of California.

Fines, Other Penalties

David, 60, has admitted to selling the device for $1,200 to $1,500 each, earning gross proceeds of about $271,000. Sandra, 55, shipped the devices and deposited the funds necessary to pay a coconspirator, David Arthur.

In an indictment unsealed earlier this year, Arthur was accused of producing the devices at his residence, which was not registered with the FDA as a manufacturing establishment. He previously pleaded guilty and is awaiting sentencing.

(See **Perez***, Page 8)*

Perez, *from Page 7*

David admitted that he intended to mislead the FDA by attempting to avoid the agency's oversight of medical claims made regarding the Energy Wave device by maintaining a separate website, rifecodes.com. He would steer customers to the site to obtain the auto codes that allegedly were effective in treating the various conditions.

In a statement, U.S. Attorney Laura Duffy chides the couple, who previously lived in Carlsbad, Calif., but now resides in Oregon, for duping vulnerable elderly patients, many of whom were suffering from incurable diseases.

"Those who are sick and desperate for relief are particularly vulnerable to scams, and we are doing our best to protect them from people who exploit the weak for their own financial gain" she says.

David is scheduled to be sentenced Jan. 11, 2016, and faces up to three years in prison and a $250,000 fine. Sandra already has received a sentence of a year of probation and 100 hours of community service. She also must pay restitution of $1,495 to a buyer of the device. — Elizabeth Hollis

FDA Warns of Infection Risk Posed by Flexible Bronchoscopes

The FDA is providing additional tips on how to reduce the risk of transmitting antibiotic-resistant infections through the proper reprocessing of flexible bronchoscopes — instruments used to check a patient's airways.

Failure to follow manufacturer instructions for reprocessing, as well as the repeated use of bronchoscopes that have integrity, maintenance or mechanical issues, continue to pose patient safety challenges, according to a safety notice issued by the agency last week.

The FDA came to this conclusion as a result of an ongoing investigation into infections associated with reprocessed reusable devices, including the complex duodenoscope. That device has been associated with infections resistant to antibiotic treatment.

A flexible bronchoscope is threaded through a patient's nose or mouth to allow a physician to examine the throat, larynx, trachea and lower airways. The FDA estimates there are about 500,000 bronchoscopy procedures performed in the U.S. annually.

In March, the FDA unveiled final guidance strengthening controls on reprocessing. At the time, it said bronchoscopes can pose a greater risk to patients if reprocessed improperly. However, the FDA has acknowledged the risk of infection transmission is lower with bronchoscopes than with duodenoscopes (*IDDM*, March 13).

To ensure patient safety, the agency is making the following recommendations for healthcare providers:

- Strictly adhere to manufacturers' reprocessing instructions;
- Remove any bronchoscope from service that fails the leak test for service and assessment of visible signs of damage;
- Follow the manufacturer's recommendations for preventive maintenance and repair of the device;
- Implement a comprehensive reprocessing quality control program to include written procedures for monitoring, training and adherence;
- Store bronchoscopes in a manner that will minimize the likelihood of contamination or collection and retention of moisture, according to manufacturer's instructions; and
- Refer to the American College of Chest Physicians and American Association for Bronchology Consensus Statement: *Prevention of Flexible Bronchoscopy-Associated Infection: 2005* for recommendations regarding bronchoscope reprocessing.

The safety notice is available here www.fdanews.com/092115-safety-notice.pdf. — Elizabeth Hollis

CDC to Healthcare Facilities: Review Your Reprocessing Practices

Citing recent reports of infection control lapses, the FDA and Centers for Disease Control and Prevention are advising healthcare facilities to ensure they are complying with device manufacturers' instructions for reprocessing reusable devices.

In a health advisory, the agencies recommend that healthcare facilities work with an expert to ensure correct device reprocessing procedures. Facilities also should train all personnel involved in reprocessing at the time they are hired or before they provide services at the facility. Personnel must show competency before performing procedures independently.

Further, employees should receive updated training at least once a year and when new devices or protocols are introduced.

The agencies also advise facilities to monitor and document adherence to cleaning, disinfection, sterilization and device storage procedures. Protocols should ensure employees can easily identify devices that have been properly reprocessed and are ready for patient use.

The advisory comes after reports of notifications, warning patients that they may be at increased risk as a result of inadequate cleaning, disinfection and sterilization of medical devices.

Earlier this year, the FDA said that between January 2013 and December 2014, it received reports involving about 135 patients infected with carbapenem-resistant Enterobacteriaceae after they were examined with a complex type of endoscope known as a duodenoscope. Antibiotic-resistant infections were reported in Chicago, Pittsburgh, Seattle and Los Angeles.

The FDA has sought to ensure adequate reprocessing, issuing final guidance strengthening controls on reprocessing in March (*IDDM*, March 13). It also provided new guidelines to help healthcare facilities in cleaning their duodenoscopes (*IDDM*, Aug. 7).

The advisory is available at www.fdanews.com/092115-CDC-advisory.pdf. — Elizabeth Hollis

FDA Seeks to Pump Up Interest in MDSAP Program

The FDA hasn't seen the expected number of industry participants in the Medical Device Single Audit Program pilot, and is hoping to attract volunteers as it eyes a Jan. 1, 2017, launch date.

The information comes from a mid-pilot report released ahead of last week's meeting of the International Medical Device Regulators Forum on the status of MDSAP, which is intended to decrease the number of regulatory audits.

Picking Up Steam?

As of July 23, 45 sites have expressed an interest in participating in the program; the target for the end of 2016 is 330 sites.

While the FDA has seen encouraging signs in terms of participation, with 20 sites signing up in July alone, there have been six months over the last year during which no volunteers came on board.

Another highlight of the status report was an update on identifying potential weaknesses of the program. During a June 23 forum, regulators, auditing organizations and manufacturers identified 15 areas of concern and 46 specific tasks intended to rectify them. IMDRF teams are reviewing the feasibility of these solutions.

In addition, IMDRF has created a quality management system that includes policies and procedures for complaints and feedback. The body encourages stakeholders to use process defined in the QMS to communicate concerns.

The organizations participating in MDSAP are the FDA, Health Canada, Australia's Therapeutics Goods Administration, Brazil's Agência Nacional de Vigilância Sanitária and Japan's Ministry of Health, Labor and Welfare and the Pharmaceuticals and Medical Devices Agency. The EU signed up as an official observer in March (*IDDM*, March 20).

The status report is available here: www.fdanews.com/092115-mdsap-review.pdf.
— Elizabeth Hollis

BRIEFS

FDA Approves ICD for MRI Scans

Device giant Medtronic has scored the FDA's blessing to market an implantable cardioverter defibrillator system for use with MRI scans — the first approval of its kind. The Medtronic Evera MRI SureScan ICD System is approved for scans on any part of the body. Previously, patients with ICD systems were contraindicated from receiving such scans because of potential interactions between the MRI and device function.

It is estimated that about 36 percent of patients implanted with an ICD will need an MRI within four years. The approval was based on safety and efficacy data from the Evera MRI global clinical trial that enrolled 275 patients.

Physio-Control Nabs Irish AED Maker

Redmond, Wash.-based Physio-Control has agreed to buy Northern Ireland's HeartSine Technologies for an undisclosed amount. HeartSine makes automated external defibrillators, and the combined company is expected to be one of the world's largest providers of AED solutions. HeartSine's offerings include the Samaritan PAD line of public access AEDs, and technologies such as CPR Advisor, which provides real-time CPR feedback.

Qualcomm Life Buys Capsule Technologie

A unit of wireless telecommunications giant Qualcomm has extended its reach into the field of medical device integration with its buyout of Capsule Technologie for an undisclosed amount. The acquisition gives Qualcomm Life, which focuses on remote home healthcare, access to Capsule's hospital clientele.

Andover, Mass.-based Capsule provides medical device integration to more than 1,900 hospitals around the world, according to a Qualcomm statement. The Capsule acquisition will allow Qualcomm to supply delivery connectivity solutions across the continuum of care — from hospital to home.

Seegene, BD Partner on Diagnostic Assays

Seoul-based Seegene has signed a pact with BD Life Sciences to develop multiplex real-time polymerase chain reaction reagents for the BD MAX system. Seegene will develop and manufacture multiplex tests based on novel technologies, while BD will have worldwide commercialization rights to these tests. Seegene CEO Jong-Yoon Chun says the agreement represents a major step in his company's expansion into the molecular diagnostics market.

Unilife Reduces Workforce

As part of a business realignment initiative, York, Pa.-based Unilife has laid off about 50 employees —about 17 percent of its workforce.

Announced during its fourth quarter and full year 2015 results, the company says the initiative will help it direct resources to support customer ramp schedules under existing supply agreements, as well as develop other relationships.

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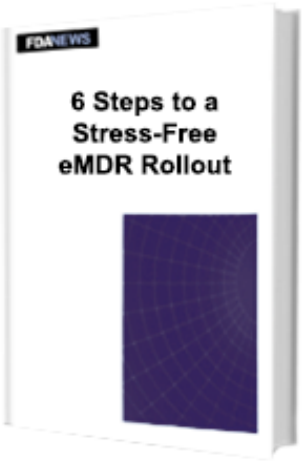

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The deadline for submitting eMDRs — August 14 — has passed. There will be NO MORE paper Form 3500As, no more MedWatch reports. Are you prepared for this major change?

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8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:45 a.m.

Pre-approval Communications

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. - 10:30 a.m.

Disease Awareness Communications

- A review of FDA's help-seeking guidance
- Keys for using disease awareness communications prior to approval. Essential information for continuing communications efforts post-approval compliantly.

10:30 a.m. - 10:45 a.m.

Break

10:45 a.m. - 11:15 a.m.

From Day of Approval through Commercial Launch

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. 12:00 p.m.

Essential Advertising & Promotion Regulations

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 1:45 p.m.

Format-Specific Promotional Requirements

- DTC television promotion
- Brief summary requirements for print promotion

1:45 p.m. - 2:30 p.m.

Substantial Evidence & Other Standards

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:00 p.m.

Off-Label Information

- Avoiding off-label promotion
- Scientific exchange exemption
- Responding to unsolicited requests
- Distributing off-label reprints

4:00 p.m. - 4:30 p.m.

The Promotional Review Process

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO | NOV. 18

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. - 9:45 a.m.

Integrating Digital Promotion

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. - 10:15 a.m.

Social Media Part 1

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:30 p.m.

Social Media Guidances

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. - 1:30 p.m.

Lunch

1:30 p.m. - 3:15 p.m.

Promotional Review Board Practicum

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. - 3:30 p.m.

Break

3:30 p.m. - 4:15 p.m.

Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent sources for keeping up with these developments.

4:15 p.m. - 4:30 p.m.

Wrap-up and Adjourn Workshop

"Dale was very engaging and informative. I like the interactive portion where we reviewed actual ads."

— 2014 Workshop Attendee

WHO WILL BENEFIT?

- Advertising and marketing managers
- Social media teams
- Promotion review committee members
- Medical affairs
- Continuing education and tradeshow organizers
- Regulatory compliance officers
- PRC coordinators
- Legal counsel
- Compliance
- Executive management
- Outside ad agencies and marketing consultants

"[Dale is] an animated speaker who seems to know something about everything and has no shortage of opinions. This is potentially very dry and dull material. Dale brings out the exciting and humorous aspects especially well. It's an engaging two days."

— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

FDA Advertising & Procedural Guidances

- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
- Presenting Risk Information Guidance
- Social Media Guidances
  - Postmarketing Submissions Requirements
  - Responding to Unsolicited Requests for Off-label Information
  - Presenting Risk Information in Space-limited Contexts Correcting Third-party Misinformation
- Distributing Off-Label Reprints

Relevant Sections of Code of Federal Regulations

Form 2253

PhRMA Principles on DTC Advertising

PhRMA Principles on Interactions with Healthcare Professionals

Pre-approval Promotion Checklist

Effective Review & Approval Process Checklist

Keys to Evaluating Promotional Review Systems List of Key Resources for Continuing Education

Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
- Patient Testimonial Videos: FDA Actions on Risk Information Presentation!
- Presenting Risk Information on Websites!
- Where Things Stand on FDA Guidance on Social Media (Publication Date of September 2014)

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