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IN THIS ISSUE

CDRH Set to Grow 3.6 Percent Under Obama's Budget Proposal

The U.S. FDA is seeking $3.8 million from Congress to establish an international courier program to boost surveillance of devices and in vitro diagnostics being imported into the country, according to the Obama administration's fiscal year 2016 budget proposal, which was sent to the Hill Feb. 2.

Overall, the Center for Devices and Radiological Health would see a 3.6 percent boost in funding to $456 million for the coming fiscal year. Of that, $327.8 million would come from congressional appropriations, up 2.1 percent over this year's $320.8 million in funding. The White House anticipates user fee collections will rise 7.7 percent, from $119.2 million this year to $128.4 million in 2016.

CDRH plans to use part of those funds to hire 49 new employees, the FDA's budget justification says.

The president's budget also prioritizes an $84.8 million agency-wide bump in medical product safety spending, raising the total to $2.7 billion. This includes $7.4 million for the precision medicine initiative and $1.9 million for continued implementation of the FDA Safety and Innovation Act.

Total Funding Up 9 Percent

Of the product safety monies, $323 million is earmarked specifically for CDRH safety programs — a $6.9 million increase over FY 2015. The center's FDASIA funds will mainly be targeted at continued implementation of the unique device identifier system.

To make things balance out, the FDA is cutting low-priority enforcement initiatives across all product centers by about $10 million. The agency did not reply to a request for comment regarding specific CDRH programs that would be trimmed.

The budget numbers are part of an overall FDA budget proposal for fiscal 2016 that would increase agency funding by 9 percent to $2.8 billion over 2015. The agency anticipates receiving $2.177 billion in overall user fees, setting total spending at $4.9 billion, with most of the increase directed at programs overseeing food and veterinary medicine.

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Budget, *from Page 1*

Other funding for medtech-related initiatives across the federal budget includes a 6 percent hike in R&D funding, including biomedical research.

The FDA's budget request is at www.fdanews.com/02-02-15-FDABudgetRequest.pdf.
— Elizabeth Orr and Bryan Koenig

Judge Approves Consent Decree For Troubled Devicemaker Maquet

A years-long standoff between the U.S. FDA and Maquet ended with a consent decree calling for the devicemaker to improve quality at its three subsidiaries.

The consent decree, signed by a New Hampshire federal judge last week, orders Maquet to shutter one of its plants until quality improves and to conduct a comprehensive remediation at all three facilities.

From 2009 to 2013, the FDA conducted 10 inspections and issued two warning letters across the three subsidiaries: Atrium Medical in Hudson, N.H.; Maquet Cardiovascular in Wayne, N.J.; and Maquet Cardiopulmonary in Rastatt and Hechingen, Germany. Maquet also initiated 45 recalls over the past five years, five of which were Class I, which designates high-risk events.

The inspections unveiled a litany of quality problems at each facility, including failure to submit a medical device report to the agency within 30 days after hearing of an adverse event for a product.

The facilities also failed to establish procedures for implementing corrective and preventive actions, and Atrium didn't have adequate procedures for device acceptance or for monitoring and controlling process parameters of a validated process, according to court filings.

Each time a facility had a poor inspection, Maquet promised to make quality improvements but didn't deliver, court filings say.

Under the consent decree, Maquet must stop making and distributing devices at its Atrium plant until it is compliant with FDA regulations. Atrium may produce medically necessary products that aren't available to patients, but can't make its Prolite Hernia Mesh, ProLoop Hernia Mesh, C-QUR Hernia Mesh, Flixene Vascular Graft and Ivena Vascular Patch.

Maquet must also pay the federal government $6 million, followed by another $6 million six months after the first payment if it doesn't get Atrium up and running, the decree says.

Finally, the devicemaker must hire a third-party expert to review the Atrium facility. The other two facilities must be audited each year by independent experts for the next four years, the decree says.

A Maquet spokesman tells *IDDM* that the company has committed about $125 million to a remediation program for the facilities. The aim is to complete all improvements by mid-2016. Excluding those costs, the consent decree is expected to cost the company $62.5 million, which includes the $6 million fine and loss of product revenue. — Robert King

Lack of Clarity, Guidance Hamper mHealth Adoption in Europe

Marketing mobile health apps in Europe may not be worth the time and effort. That's the conclusion of a majority of the 211 stakeholders who weighed in on a 2014 European Commission consultation on mHealth issues.

According to a recent Green Paper, commonly cited barriers include lack of a clear regulatory framework and overly complex legislation, difficulties providing scientific evidence, lack of interoperability and common quality standards, and knowledge gaps between app makers and potential users.

Of those responding, 46 percent believe strong privacy and security tools, such as

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authentication and data encryption, are needed to build user trust. Such tools should follow technical recommendations made by the Article 29 Working Party, which represents the views of data protection authorities in EU member states. An equal number of commenters want stronger enforcement of existing data protection rules.

And despite concerns about the risks of over-regulation, many stakeholders would like to see increased scrutiny of health and wellness apps that are not covered under current rules. Thirty-four percent say any performance or safety rules applied to wellness apps should be clarified in legislation, guidance or self-regulation and nearly half want some kind of certification of lifestyle and wellbeing apps to ensure patient safety and information transparency.

Want More Clarity On Liability

Stakeholders also want the Commission to provide more clarity on liability issues around mHealth, possibly through drafting guidelines or an industry code of conduct. Risk-mitigation strategies and reporting mechanisms are also suggested as solutions.

Other comments suggest updating reimbursement systems to pay for mHealth and encouraging adaptation of international standards.

Commenters also call for more studies on the benefits of mHealth, with 21 respondents citing research by Boston Consulting Group that found mHealth use could cut rehospitalizations and nights in the hospital by 50 to 60 percent in some age and disease categories.

The green paper reflects concerns of European devicemakers about the need for data protection and privacy, interoperability of e-health technologies and a clearer legal framework that would include clear definitions of wellness products and medical devices, says Eucomed spokesman Thomas Lindemann. “Most of our ideas have been included in the final report,” he adds.

Devicemakers comprised the largest block of commenters at 33 of the 211. Of the remainder, 25 came from national or regional regulatory authorities, 21 from medical professionals, 18 from research groups and the rest came from patient groups, insurers, nongovernmental organizations and web entrepreneurs.

View the Green Paper at www.fdanews.com/02-09-15-mhealth.pdf. — Elizabeth Orr

U.S. FDA Commissioner Hamburg Departing at End of March

Margaret Hamburg has resigned as commissioner of the U.S. FDA, effective at the end of March, ending a six-year tenure that saw the agency speed up its device approval process and increase its focus on personalized medicine.

Under Hamburg’s watch, the agency’s budget rose by nearly $2 billion — from $2.7 billion in fiscal year 2009 to $4.5 billion this year. Janet Trunzo, AdvaMed’s senior executive vice president for technology and regulatory affairs, said Hamburg was instrumental in getting the 2012 MDUFA III user fee legislation adopted, which brought additional resources, accountability and resources to the device center.

FDA Chief Scientist Stephen Ostroff will take over the commissioner’s post temporarily. There is no word from the White House on who it will nominate to fill the post, but some have suggested Duke University cardiologist Robert Califf, the newly appointed deputy commissioner, as a logical choice (*IDDM*, Feb. 2).

Hamburg’s six years represents the longest tenure in the commissioner’s office since David Kessler served from 1990 to 1997. In a resignation letter sent to staff Thursday, Hamburg touted the agency’s role in ushering in an era of personalized medicine. She also noted that the number of days to PMA approval has dropped by a third since 2010, and commented with pride on the development of the unique device identifier system and the proposed regulatory framework for laboratory-developed tests. — Lena Freund and Elizabeth Orr

ONC Outlines Challenges, Next Steps to Health IT Interoperability

The federal office that oversees health IT in the U.S. wants devicemakers to clarify privacy and security requirements that enable device interoperability, with the aim of achieving nationwide interoperability by 2017.

To that end, devicemakers should work with the Department of Health and Human Services, the Food and Drug Administration and others in the health IT arena to create a coordinated framework for nationwide interoperability. This framework should be supported by technical standards and guidance on sharing and using a common clinical data set, according to a roadmap by the Office of the National Coordinator for Health Information Technology.

Increasing use of mobile health technologies and the switch to electronic health records has made interoperability key to ensuring all systems perform properly and communicate with one another when necessary.

More Flexibility Needed

Achieving this goal will require more flexible approaches, as well as leveraging modular consumer applications such as those created by Facebook, Amazon and Apple, ONC says. These products allow users to access health information on different platforms and devices and provide a business opportunity for third parties.

Challenges to nationwide interoperability in the U.S. include the fact that health IT information is not always structured or standardized to be fully computable when accessed, ONC says. It can also be difficult to automate externally derived electronic health information in the desired way. A lack of financial incentives, misinterpretation of laws and nonaligned laws and policies also limit electronic information sharing, ONC says.

To facilitate information sharing, ONC recommends a market-based network approach similar to what has been done in the telephone and banking industries.

HHS will assess what additional guidance on current legal requirements, including patient privacy protections, may be necessary, the office says.

ONC plans to analyze and report on U.S. progress toward interoperability through the Health IT Dashboard, which allows it to identify and share information on challenges and next steps.

To read the roadmap, go to www.fdanews.com/02-09-15-interoperability.pdf. — April Hollis

Expert: Optimize Trials as CMS Coverage Narrows

The U.S. Centers for Medicare & Medicaid Services increasingly wants to see evidence of positive outcomes before it will cover a medical product, according to a new study that found recent coverage determinations 20 times less likely to be positive than in the past.

The researchers looked at national coverage determinations from February 1999 to January 2002 and then again from March 2008 through August 2012. The more recent NCDs were far more likely to include evidence of a positive effect on outcomes, rather than relying on surrogate endpoints, the authors say.

CMS is also increasingly using "coverage with evidence development" to restrict coverage to patients enrolled in a clinical trial or registry while more evidence is gathered, the study notes. It was published in the February issue of *Health Affairs*.

Meanwhile, health technology assessments are playing a greater role in coverage policy, and a trend toward comparative-effectiveness research has led to more payers comparing competing products, the authors write. If alternative products are available and CMS lacks an estimate of cost-effectiveness, these factors lower the chance of Medicare coverage even though cost-effectiveness evidence is not required in national coverage determinations, they add.

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Medicare, *from Page 5*

Despite these shifts, many devicemakers are not including Medicare beneficiaries in their clinical studies, study author James Chambers tells *IDDM*.

While the study doesn't say whether there should be greater use of the parallel review process, Chambers says Medicare decisionmaking is fairly consistent with the evidence the FDA reviews. This suggests that parallel review has great potential, he says.

Chambers advises devicemakers to engage CMS early and often, and whenever they have any evidence that might support Medicare reimbursement.

Manufacturers should also include more Medicare beneficiaries in their studies, as this is "a huge thing" for the agency, he says. For older populations, the trials should show an improvement in health outcomes due to hard endpoints, rather than surrogate endpoints, he adds.

The study also notes a positive association between coverage decisions and favorable recommendations in clinical guidelines. This "suggests that the weight of professional opinion also influences CMS decisionmaking," the authors say.

AdvaMed CEO Stephen Ubl says the study underscores that the increasing weight given to evidence requirements is slowing patient access to new medical technologies.

Chambers, an assistant professor at the Tufts Medical Center Institute for Clinical Research and Health Policy, hopes the study will spur greater transparency in evidence requirements with CMS and other payers, ideally speeding access to new technologies. — April Hollis

Regulations Fueling Growth In Malaysia's Device Market

Growth in healthcare services in Malaysia is expected to drive consumption of medical devices in the coming years, market analysis firm Frost & Sullivan says. The rosy forecast comes as the deadline approaches for registering certain products in the country.

In-country production of medical devices will include orthopedic products, dialyzers, surgical instruments, medical electrodes, diagnostic radiographic equipment and ophthalmic lenses, Frost & Sullivan says in a new report.

Under the 2012 Medical Device Regulations, devices newly entering the Malaysian market had to be registered by July 1, 2014. Devices previously exported, imported or placed in the market got a 24-month grace period, meaning they must be registered by July 1 of this year.

That has foreign companies rushing to get approval now, says Ames Gross, president of Pacific Bridge Medical.

According to Frost & Sullivan, the Southeast Asian device market is heavily reliant on imports, especially for high-end and sophisticated medical equipment. In the major economies, the value of device sales to healthcare facilities was worth US $4 billion in 2013.

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Malaysia, *from Page 6*

That number is expected to double by 2019 as regulatory harmonization fuels manufacturing investments and flow of medical goods, and as tougher regulatory crackdowns improve compliance with ethical promotion practices, the report says.

Malaysia's transition from an unregulated market to a regulated one is viewed as positive by investors, says Zamane bin Abdul Rahman, chief executive of the country's medical device authority. Intense competition among bona fide manufacturers producing quality devices will create a level playing field, as the country works to eliminate substandard products and spurious products, he tells *IDDM*.

The Malaysian government has made a significant effort to spur investment in medical devices, including providing incentives to build manufacturing plants. As for exports, the new regulations will have a tremendous impact on costs and quality of locally made products, whether finished or otherwise, says Rahman.

While regulation has been good for Malaysia's device market, the approaching registration deadline probably isn't, says Nitin Dixit, industry manager of healthcare for Frost & Sullivan Asia Pacific. The Medical Devices Control Division has authorized just five notified bodies to do conformity assessments, leading to delays in the registration process, Dixit tells *IDDM*.
— Jonathon Shacat

New Forms for U.S. MedWatch System Due Out This Spring

The U.S. FDA will roll out a simplified adverse event reporting form this spring in hopes of getting more consumers to use its MedWatch system, agency officials said Wednesday.

The agency also hopes to broaden use of its MedWatcher smartphone app, which allows quick submission of voluntary MDRs that may include photos, says Stephanie Joseph, a biomedical engineer in the FDA's Office of Health & Constituent Affairs.

The new report forms, which become mandatory on July 1, add checkboxes allowing submitters to note the patient's age in years, weeks, months and days, which may be helpful for reports involving infants, Joseph says. She spoke at a webinar hosted by the American Academy of Medical Instrumentation.

The 3500B consumer form is one of three debuted in a December *Federal Register* notice of upcoming changes to both paper and online versions of the forms. The others are the 3500 for healthcare providers and 3500A for devicemakers.

Exemptions Possible

William Maloney, a physicist in the FDA's device center, sought to clarify exemptions to mandatory MDR reporting. These include an alternative summary report — a periodic summary of all adverse events for devices that have been on the market for at least two years, a remedial action exemption for further reports of device failures collected while a recall is already underway, and the single MDR exemption, which allows for a single form to be submitted per incident if there are multiple mandatory reporters in play.

To request a single MDR exemption, devicemakers and importers should send an email to mdrpolicy@fda.hhs.gov briefly explaining the situation and including registration and listing information for the possible reporters. FDA staff will respond with advice, Maloney says.

Injuries should normally be reported via MDR if they require medical treatment, Maloney says. For example, a cut from a jagged edge of a device that required stitches would need to be reported, while a scrape would not. But the ultimate definition of "serious injury" is decided by the staff at the user facility, he says.

View the FDA's announcement of the changes at www.fdanews.com/02-09-15-MDRs.pdf.
— Elizabeth Orr

Online Registration System Going Live Feb. 11 in UK

Starting Feb. 11, makers of Class I devices, custom-made devices, custom-made active implantable devices and in vitro diagnostics can register in the UK using an online system.

Use of the Devices Online Registration System will be voluntary until May 11, when the Medicines and Healthcare products Regulatory Agency will stop accepting paper registrations. Companies that register via the new system will be able to directly manage their details, the MHRA says.

The two-step process involves submitting contact details for the manufacturer, authorized representative or assembler and, upon activation of the account, register the organization and related devices.

MHRA will charge a fee of about U.S. $105 for new registrations and for making certain changes. Companies that are currently registered need to create an online account only if they want to make changes to their details or register a new device.

DORS can be accessed at https://aic.mhra.gov.uk/era/drsystem.nsf/login. — Jonathon Shacat

FTC: Increasing Connectedness Of Devices a Growing Concern

Specific laws around the marketing and use of internet-connected health devices may not be necessary, but better data security laws probably are, the U.S. Federal Trade Commission concludes in a new report on device security in the internet age.

According to the FTC, the "internet of things" refers to everyday objects that can capture and send data to and from the internet. There are currently about 25 billion internet-enabled devices in use, and that number is expected to double by 2020, the report says.

The 71-page report, drawn from discussion at a November 2013 FTC workshop, groups internet-enabled health devices with other products such as cameras and phones, but includes a number of specific health device scenarios.

Workshop attendees agreed that current devices aren't secure enough, with known risks including unauthorized access and misuse of personal information, leading to attacks on other systems, and risks to personal safety. Strategies to combat these risks include incorporating security measures in devices from the design stage and minimizing the amount of data that internet-connected devices collect, the report says.

The report also suggests making data collection opt-in via such tools as a privacy dashboard, QR codes on devices, or providing choices at the point of sale. Companies that plan to use data in a way that isn't self-evident should ensure a way to inform customers, the FTC says.

Overregulation a Fear

The report stops short of recommending regulatory changes that would protect data collected via networked devices. Overregulation at this point could harm the nascent industry, the FTC says. In the place of regulations, the report suggests self-regulation, consumer education and industry best practices.

Some attendees worried that data from "internet of things" devices would be used to set health, automobile or other insurance premiums. To combat that concern, Congress should enact "strong, flexible and technology-neutral legislation" that strengthens the FTC's ability to enforce data security rules and require companies to notify consumers of a security breach, the report suggests.

The FTC also recommends that Congress to set baseline privacy standards for use in developing guidance on when companies must notify consumers about data collection and use.

View the report at www.fdanews.com/02-09-15-internet.pdf. — Elizabeth Orr

Chinese Regulator Looking To Ramp Up Device Quality

The China Food and Drug Administration plans to beef up its inspections system for medical devicemakers by adding more investigators and improving the performance of quality testing centers.

The changes, outlined in Jan. 23 draft guidance, also call for stronger leadership at the CFDA and provincial and local FDAs, better staff training, greater information sharing, enhanced research capacity and a more coordinated approach.

The CFDA appears to planning to conduct more inspections on an announced basis, says Jack Wong, director of regulatory affairs for Asia Pacific in TerumoBCT's Singapore branch. The changes being proposed to the inspections infrastructure will be good for industry in the long term, but could slow audits and submissions that rely on positive audits in the short term, he tells *IDDM*.

The guidance, which lacks details, is mainly a set of goals that the CFDA hopes to attain, says Seth Goldenberg, director of global regulatory strategy at NAMSA. Devicemakers can expect more specifics on the reforms over the next several years, he predicts.

Read the CFDA's guidance document, in Chinese, here: www.fdanews.com/02-15-CFDA-Guidance.pdf. — Jonathon Shacat

Industry Finds Little to Be Happy With in Proposed LDT Regulation

Devicemakers took aim at a range of issues in the U.S. FDA's proposed framework for regulating laboratory-developed tests, from definitions for exempt LDTs to the impact on innovation and strain on FDA resources.

The FDA already struggles to process premarket applications for in vitro diagnostics and would be further slowed if resources are stretched to include LDTs, says PerkinElmer. The company was one of several to urge the agency to delay LDT oversight until after a formal rulemaking process that includes notice and comment period and a risk/benefit analysis.

Start-up firm GeneCentric Diagnostics complained that FDA regulation could keep labs from quickly updating tests, leading to locked-in, outdated assays. Such stagnation could inadvertently harm patients, the company said.

Under the risk-based framework proposed by the FDA, regulated labs producing high-risk LDTs would have to get premarket approval beginning two years after the release of final guidance. Premarket authorization for lower-risk LDTs would be phased in over nine years.

Exemptions

Commenters also took issue with plans to exempt tests used in a single hospital or healthcare system from regulation. There is no clear way in which such "traditional LDTs" pose a higher risks than tests that are more broadly available, Invitae said.

And PerkinElmer argued that if traditional LDTs are exempt from regulation, then the agency should also exempt tests made in independent labs that are CLIA-certified or similarly accredited.

Devicemakers also urged the FDA to reconsider its definition of an LDT for a rare disease as one performed fewer than 4,000 times a year, saying the agency should use the Orphan Drug Act's definition of a disease that affects fewer than 200,000 people in the U.S. Under the FDA's proposal, these would also be exempt from federal oversight. Nearly 230 comments were submitted on the October draft guidance by the Feb. 2 deadline.

Traditionally, LDTs have been regulated by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments, or CLIA. However, the growing use of the tests to drive decisions about patient care and their increasing complexity — resulting in sophisticated tests that resemble fully regulated commercially distributed IVDs — led the FDA to consider a more active role. In 2013, FDA Commissioner Margaret Hamburg announced

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agency plans to regulate LDTs. A formal proposal was submitted to Congress last August.

AdvaMedDx asked the FDA to add a "safe harbor" to encourage established devicemakers to provide resources and advice to labs during the submission and approval process. The proposed framework suggests that may be viewed as unlawful promotion, which could scare off partnerships, the trade group said. The group also wants the FDA to protect companies that legally sell research-use only tests to clinical labs. Regulation of LDTs could force manufacturers to police the ways customers use ROUs.

Other comments echoed concerns that FDA regulation of LDTs would involve the agency in practice of medicine (*IDDM*, Jan. 29). Invitae noted that LDTs must be interpreted by qualified medical professionals in a process that overlaps devices and the practice of medicine. Final guidance should clarify that LDT interpretation and communications between the lab and doctors treating patients is not subject to FDA review, the company said.

View all of the comments at www.regulations.gov/#!docketDetail;D=FDA-2011-D-0360. — Elizabeth Orr

U.S. FDA: Implantable MIGS Devices Need 12 Months Clinical Follow-Up

Sponsors of implantable, minimally invasive glaucoma surgical devices should follow clinical trial subjects for at least a year before submitting an application, the U.S. FDA says.

If the follow-up will be less than two years, the sponsor should provide justification based on a risk-benefit analysis, according to the draft guidance issued Feb. 11. Clinical trial participants should show signs of early or moderate open-angle glaucoma.

Effectiveness endpoints should include washout, primary effectiveness, secondary effectiveness and recommended analyses. The primary effectiveness endpoint should be the percentage of subjects with reduction of at least 20% (i.e., ≥20%) in mean diurnal intraocular pressure from baseline, the FDA says. Sponsors should describe the proposed hypothesis test for the primary endpoint in their statistical analysis plan. For the secondary effectiveness endpoint, the guidance recommends using the mean diurnal intraocular pressure change from baseline.

The guidance also gives advice on nonclinical testing, noting it should be performed on the finished sterilized product.

Sponsors should refer to ANSI Z80.27 for adverse events and malfunctions for minimally invasive glaucoma surgical devices, the guidance says. The definition of each adverse event should specify severity, impact on the anatomical structure, timing and the duration of the event.

Devicemakers' case report forms should include a forced-choice method for recording listed adverse events and a method of recording other adverse events that are not listed.

Comments are due May 12 on the draft, which is available at www.fdanews.com/02-05-15-Glaucoma.pdf. — April Hollis

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Mr. Cooke's practice specializes in helping FDA-regulated companies develop compliant promotional tactics and improve the promotional review. He is the author of ***Effective Review and Approval of Digital Promotional Tactics*** and is currently at work on a book about compliant social media usage for prescription product manufacturers.

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

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DAY ONE | MAY 13

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 | MAY 14

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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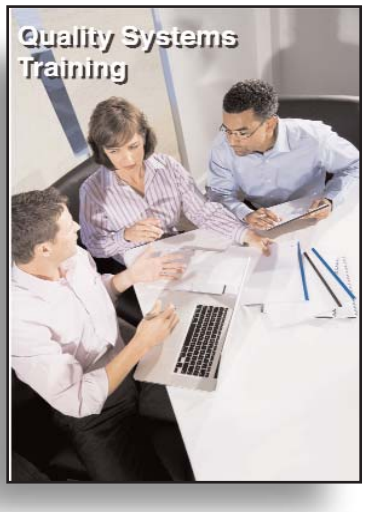

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