Implementing Effective Regulatory Controls that Overcome Off-Label Challenges and take into Account the Evolving Enforcement Environment with Permissive & Mandatory Exclusions and Individual Liability

DISTINGUISHED PRESENTERS INCLUDE:

Perry Goldman  
Vice President, Legal Affairs  
ACTELION PHARMACEUTICALS US, INC.

Michael Rogoff  
Partner  
KAYE SCHOLER

Shane Freedman  
Vice President - Law  
ETHICON, INC.

Sara Dyson  
Assistant VP, Loss Control  
MEDMARC INSURANCE GROUP

Tracy Blumen  
Associate Director Compliance  
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Richard Lanzillotto  
Director of Quality Affairs and Quality Assurance  
IMACOR INC.

Fred Taccolini  
VP, Compliance Officer  
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Matthew D’Ambrosio  
Senior Vice President, Chief Compliance and Ethics Officer  
SUNOVION PHARMACEUTICALS

Inna Kissen PhD  
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Michael Shern  
Sr. Counsel, Legal Department  
GENZYME CORP.

David Restaino  
Partner  
FOX ROTHSCHILD LLP

Jean Frydman  
US Chief Counsel & Chief Compliance Officer  
FERRING PHARMACEUTICALS

Areta Kupchyk  
Partner  
REED SMITH

Linda Politz  
Director Regulatory Affairs, Advertising & Promotional Labeling  
ALKERMES

Peter Clark  
Exclusion Director  
OIG  
*Pending Final Confirmation

PROGRAM OVERVIEW:

As the number of off-label promotion cases against pharmaceutical and medical device corporations and corporate executives continues to increase, the industry continues to consider measures to be implemented to provide guidance and support to their executives, in an effort to maintain rigorous compliance. Through a series of presentations over the course of two days, from organizations including FDA, the OIG, as well as leading pharmaceutical and medical device firms, executives will gain a firm understanding of compliant uses of off-label information. With a strong speaker platform with dozens of years of combined experience, this program will be a must-attend for the pharmaceutical and medical device industries.

One of the primary drivers of the program will be gaining a closer understanding of new individual liabilities as related to the communication of potential off-label uses. Recent developments and cases involving industry executives and the OIG has many in industry concerned not only about organizational compliance, but also the compliance of internal executives who may face prosecution. Revised policies and procedures, including RCOD will be addressed. Also being covered will include recent cases including the highly publicized Forest Labs case, as well as individual liability provisions in corporate integrity agreements. Also integral to the conference program will be sessions focusing on the increasingly concerning Anti-Kickback, FCPA and other topics of great relevance to today’s compliance executive. While off-label communication is only part of the overall compliance picture, it is an increasingly critical component of the overall compliance strategy. As with all Q1 productions programs, the focus of this agenda will not only include case study presentations, panel discussions and hands-on workshops, but will also focus on informal networking and knowledge share. With a sterling reputation for bringing together high level industry executives, this program will certainly be a highlight within the 2011 conference calendar.
ACTELION PHARMACEUTICALS US, INC.
Vice President, Legal Affairs
Perry Goldman

• Debating intent vs non-intent
• Key takeaways from the Stevens case
• Clarification of obstruction and false statement charges
government fraud prevention agencies.

While Stevens was ultimately granted a judgment of acquittal, the case il
but does provide more factual details, including quotes from the defendant.
original case was dismissed in March due to allegations of the grand jury be
In April of 2011 Lauren Stevens, who was accused of allegedly obstructing
a federal probe into off-label marketing of a drug, was re-indicted after the
11:35

OIG
Peter Clark

• Exclusions within CIAs
• Comparing and contrasting permissive vs mandatory

10:30
COFFEE & NETWORKING BREAK

10:50
CLAIRIFYING PERMISSIVE & MANDATORY EXCLUSIONS IN DEVICE & PHARMA SETTLEMENTS

Misconduct charges brought against executives in the device and pharma-
caceutical in 2010 shocked the industry, leading many to believe that the
government will focus on increasing accountability of owners, officers and
managing employees of sanctioned entities. While the permissive exclusion
authority for individuals controlling a sanctioned entity has been in effect
since 1996 (HIPPA), it has only recently been enforced. On November 16,
2010, the OIG announced the exclusion of Marc Hermelin from participation
in federal health care programs after he pleaded guilty to violating labeling
laws. This is believed to be the first case in which a drug company executive
who has not been personally convicted of wrongdoing has been banned from
participating in federal health care programs.

• Defining permissive and mandatory exclusions
• Comparing and contrasting permissive vs mandatory
• Exclusions within CIAs

Peter Clark
Exclusion Director
OIG

*Pending Final Confirmation

11:35
OBSTRUCTION & FALSE STATEMENTS: AN IN-DEPTH ANALYSIS OF THE STEVENS CASE

In April of 2011 Lauren Stevens, who was accused of allegedly obstructing
a federal probe into off-label marketing of a drug, was re-indicted after the
original case was dismissed in March due to allegations of the grand jury be-
ing misled. The new indictment largely bears a resemblance to the original,

Michael Rogoff
Partner
KAYE SCHOLER

• Forecast and analysis of new OCI criteria
• Key takeaways from RCO
• Forest Labs case and its’ effect on the industry
• Future liability trends

1:40
UPDATING RECENT ACTIVITIES IN SOCIAL MEDIA & OFF-LABEL PROMOTION

Although the FDA has indicated on a number of occasions that they will de-
velop formal guidance to govern the promotion of drugs and devices through
social media outlets, the industry has yet to view any regulation on this type
of interaction with the public. While the FDA’s 2011 agenda did provide guidance
on “Responding to Unsolicited Request for Prescription Drug and Medical De-
vice Information, Including those Encountered on the Internet”, the subject of
“Promotion of Prescription Drug Products Using Social Media Tools” was over-
looked. Device and drug companies struggle to develop appropriate social
media compliance policies and procedures as social media networks continue
to skyrocket.

• Analyzing FDA’s 2011 guidance agenda
• Best practices and case studies for developing compliant social media policies
• Will there ever be answers?

Areta Kupchyk
Partner
REED SMITH

2:25
PANEL: DISCUSSING OFF-LABEL RELATED INVESTIGATIONS & EXPOSURE

A number of recent compliance cases and settlements within the device
and pharmaceutical industries have focused on additional areas of concern
relative to off-label promotion allegations, and it is critical that compliance
teams stay abreast on and have a thorough understanding these issues.
By highlighting and analyzing significant off-label related cases, compliance
teams will gain a greater perspective on key areas of concern for regulators
to further the development of compliant policies and systems. The following
discussion will provide industry insight and guidance on off-label related top-
ics while specifically addressing:

• False statements and documentation controls
• Adulterated therapies and products
• Instances involving fraud

Michael Rogoff
Partner
KAYE SCHOLER
Shane Freedman
Vice President: Law
ETHICON, INC.

3:25
COFFEE & NETWORKING BREAK

3:45
OFF-LABEL PROMOTION & PRODUCT LIABILITY

Most manufacturers are aware that off-label promotion can lead to enforce-
ment actions, the most serious of which result in fines and criminal prosecu-
ction. However, manufacturers often are not aware that off-label promotion
can give rise to products liability lawsuits that may significantly impact cor-
porate reputations and balance sheets. To avoid products liability lawsuits,
manufacturers need to be familiar with several, key legal concepts and re-
lated risk management strategies.

• Overview of product liability claims
• In-depth analysis of claims specific to off-label allegations
• Strategies to forecast and limit product liability claims

Sara Dyson
Assistant Vice President, Loss Control
MEDMARC INSURANCE GROUP

4:30
KICKBACKS & OFF-LABEL PROMOTION

Two of the top three areas in which non-compliance actions are most com-
mon include kickbacks and off-label promotion; and the US Government, led
by the Department of Justice has been focusing their attentions on this area
and the life science industry for the past several years. Therapies and devices
are assessed to determine their safety and effectiveness, while physicians
and healthcare providers are tasked with providing the most reliable and ef-
ficient solutions to patients. The industry has become one of the most heavily
scrutinized in instances such as consulting contracts with physicians– pay-
ments for doing a small amount of work for a large amount of money–or in a
sales setting where a physician inquires on an off-label use of a therapy and
the representative responds with the information.

Jean Frydman
US Chief Counsel & Chief Compliance Officer
FERRING PHARMACEUTICALS

5:15
DAY ONE CONFERENCE CONCLUSION
DAY TWO / FRIDAY, NOV. 4

8:00 REGISTRATION & CONTINENTAL BREAKFAST
8:45 CHAIRPERSON’S OPENING REMARKS
9:00 EXPLORING THE NATURE OF SCRUTINY SURROUNDING OFF-LABEL INFORMATION

In the past ten years, the pharmaceutical industry, and more recently the device industry, has received a great deal of scrutiny surrounding off-label promotion allegations. Recent cases are significant not only because of their high fines, but also due to the methods in which the government prosecutes the manufacturers. While many organizations have worked diligently to combat these compliance issues, new areas of government scrutiny continue to emerge.

- Enforcement waves of the past decade
- Defining recent areas of government investigation
- Clarifying gray areas of off-label promotion

David Restaino, Partner
FOX ROTHSCHILD LLP

9:45 WORKSHOP: DEVELOPING COMPLIANCE PROGRAMS THAT INCLUDE OFF-LABEL COMMUNICATION

The following presentation and panel discussion will focus on the mechanics and potential off-label promotion liability, and compliance teams need to work tirelessly to develop the most ethical and prudent policies and procedures. Potential off-label promotion liabilities in addition to the emerging focus of individual liability have compliance departments making off-label promotion compliance a top priority. By implementing strict off-label compliance policies, it’s imperative that compliance officers are aware of what the ways in which their colleagues and competitors prevent risk.

- Cross-industry off-label best practices
- Proactive monitoring and auditing strategies
- Case studies specific to device and pharmaceutical

Fred Taccolini, Vice President, Compliance Officer
PIONEER SURGICAL

11:00 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:00 UNCONFERENCE BREAKOUT SESSION

Breakout sessions will be conducted in an unconference format. Conference participants will identify topics they wish to discuss further in smaller groups. From there, conference facilitators will take volunteer moderators from the audience to lead each discussion. Through the unconference format, all attendees, speakers and sponsors are encouraged to become active participants allowing for better exchange of ideas, peer-to-peer learning, and open discussion.

3:00 WORKSHOP: MAINTAINING A COMPLIANT SALES PROGRAM

The following two presentations will focus on the challenges and opportunities in creating and maintaining compliant sales processes. After formal presentation, attendees will have an opportunity to discuss these challenges in a smaller-group setting.

CREATING & IMPLEMENTING COMPLIANT SALES TRAINING PROGRAMS

Developing sales and marketing training programs for both the pharmaceutical and medical device industries can be a significant challenge for executives, particularly in the area of off-label information. Compliance departments are responsible for producing appropriate sales protocols, educating their sales teams on how to use these and understanding the function and importance of these procedures as a whole. Conveying the seriousness of complex off-label compliance issues to sales and marketing teams can potentially reduce off-label-related liabilities—both organizationally and individually.

- Methodologies and tools to properly prepare sales teams
- Analyzing communication trends between sales reps & healthcare providers
- Critical high risk sales areas and potential solutions

Elise Roth, Counsel
BAYER HEALTHCARE

COMPLIANT DRUG & DEVICE PROMOTION: BEST PRACTICES FOR SALES REPS & CONSULTANTS

The presence of off-label promotion is well illustrated by the number of companies under corporate integrity agreements with the DOJ. Due to the common occurrence of this type of settlement agreement, many manufacturers have implemented stringent restrictions regarding what can and cannot be said about a device or drug by requiring sales representatives and physicians/HCP providers speaking on the company’s behalf to stick to a scripted presentation. This repetition of the company message has not been well received by physicians and healthcare providers and needs to be re-evaluated to retain positive relationships.

- Developing compliant and credible messages for reps and physicians
- Defining avoidable areas of liability
- Guidance on unsolicited information

Linda Pollitz, Director Regulatory Affairs, Advertising & Promotional Labeling
ALKERMES

4:30 CLOSING REMARKS & CONFERENCE CONCLUSION
ATTENDEE PROFILE:
Individuals that will find this program of greatest interest and applicability will be those responsible for the monitoring of off-label information and use throughout pharmaceutical and medical device corporations. With presenters bringing dozens of years of expertise to the program agenda, this conference program will be a must attend for those looking to remain up to date with recent and ongoing investigations. Executives with the following job titles will find this program of the greatest applicability:

- Compliance Officers
- Regulatory Affairs Executives
- Corporate Counsel
- Legal Affairs
- Promotion Compliance
- Advertising Promotion
- Labeling Compliance

PREVIOUS ATTENDEES INCLUDE:

- Assistant Director, US Labeling, ABBOTT LABORATORIES
- Director, Policies & Procedures, ABBOTT LABORATORIES
- Ethics & Compliance Officer, ABBOTT LABORATORIES
- Director, Corporate Compliance, ALCON LABORATORIES
- Sr. Director, Promotional Compliance, ALLERGAN
- Sr. Manager, Healthcare Compliance, ALLERGAN
- Director of Compliance, AMGEN
- Executive Director, AMGEN
- Director of Compliance, AMYLIN PHARMACEUTICALS
- Corporate Counsel, ASCENSION ORTHOPEDICS
- VP & Chief Regulatory Counsel, ASTELLAS
- Chief Compliance Officer, ASTELLAS
- Associate General Counsel, AUXILIUM PHARMACEUTICALS
- VP Corporate Compliance, B. BRAUN MEDICAL
- Director, Advertising & Promotion, BAUSCH & LOMB
- Compliance Monitor, BAYER HEALTHCARE
- Associate Director, Regulatory Affairs, BAYER
- Chief Compliance Counsel, BIOMEDICINE
- Chief Compliance Counsel, CARDIAN BCT
- Associate Director, Regulatory Affairs, CELGENE
- Director, Healthcare Compliance, CORDIS
- Assistant General Counsel, DAICHI SANKYO
- Assistant General Counsel, ELI LILLY
- Sr. Director, Ethics & Compliance, ELI LILLY
- Director, US Regulatory Affairs, EMD SERONO
- Product Promotions Mgr., FERRING PHARMACEUTICALS
- Chief Compliance Officer, FERRING PHARMACEUTICALS
- Compliance Manager, FOREST LABORATORIES
- Corporate Counsel, GENENTECH
- Associate Director, ADVERTISING PROMOTION, GENZYME
- Director, Regulatory Affairs, GILEAD SCIENCES
- Compliance Director, GLAXOSMITHKLINE
- Assistant General Counsel, INVACARE CORPORATION
- Sr. Director, Corporate Compliance, JAZZ
- Sr. Director, CIA Management, JOHNSON & JOHNSON
- VP Healthcare Compliance, JOHNSON & JOHNSON
- Sr. Director, Governance Monitoring, JOHNSON & JOHNSON
- VP Healthcare Compliance, KINETIC CONCEPTS INC.
- Chief Compliance Officer, LUNDBECK
- Chief Compliance Officer, MCKESSON
- Director, Regulatory Affairs, MEDITATION
- Sr. Director, CIA Management, JOHNSON & JOHNSON
- Head of Ethics & Compliance, NOVARTIS
- Sr. Compliance Counsel, OTSUKA
- VP & Chief Compliance Officer, OTSUKA
- Chief Compliance Officer, PIONEER SURGICAL
- VP Global Regulatory Affairs, SHIRE
- Compliance Officer, SIEMENS HEALTHCARE DIAGNOSTICS
- Compliance Officer, SMITH & NEPHEW
- Compliance Officer, SPECTRUM PHARMACEUTICALS
- Associate General Counsel, SUNOVIAN PHARMACEUTICALS
- Chief Compliance Officer, SYSTAGENIX WOUND MGMT
- Compliance Officer, TEVA PHARMACEUTICALS
- Deputy General Counsel, TEVA PHARMACEUTICALS
- General Counsel, VALIDUS PHARMACEUTICALS
- General Counsel, VASCULAR SOLUTIONS
- Chief Compliance Officer, WATSON PHARMACEUTICALS

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