PHA6279 – Spring Seminar

Saturday 4 March – Sunday 5 March 2017

1 Credit

Expanding Drug Use Information Communication

Implications of the FDAMA section 114 and Off-Label Information on Patient Care

Seminar Overview

The FDA approves drugs for marketing in the US, which includes control over approved drug labeling. The product "label" includes all information communicated on and with the drug package and collateral promotional information to health care professionals and the public. However, prescribers and health care system decision makers are not bound to consider and use only approved "on-label" information when selecting drugs for individual patients and drug formularies, and often request off-label information from pharmaceutical manufacturers. New drug "dossiers", often following AMCP Format for Formulary Submission[1] format, are provided to formulary decision makers, and often include off-label data, marketing information, and unpublished "data on file" not in compliance with FDA promotional guidelines. Dossiers must be unsolicited, and may not be distributed to prescribers.

The 1997 FDAMA section 114 intended pharmaceutical manufacturers to provide economic information on approved drug uses to formulary decision makers, but the vague safe harbor language prevented general use. The FDA now proposes to revise section 114 to facilitate economic data communications that are requested and used by formulary decision makers. Some pharmaceutical manufacturers believe they should be allowed to communicate truthful, off-label information to both prescribers *and* formulary decision makers, as such data are already being published and used. Recent court decisions (Caronia, Amarin, others) have affirmed truthful off-label communications in specific situations may be allowed and protected by the First Amendment, despite opposition by the FDA. Some of the issues this seminar will probe include the following:

- Will other pharmaceutical companies boldly challenge the FDA compliance policies and attempt to communicate truthful off-label information to health care professionals? Will this erode FDA efforts to control unsafe and unproven drug use?

[1] AMCP Format for Formulary Submission 4.0 available at http://www.amcp.org/FormatV4/.

- How do health care formulary decision makers now use off-label drug information? What unmet clinical and economic information data do are requested from manufacturers?
- How will the FDA respond to these issues and challenges? Will the FDA consider economic information in drug approvals? How will the FDAMA section 114 update impact economic drug information communications? How are manufacturers using section 114 to provide economic information?
- How are manufacturers now using the AMCP Format ("dossier") to communicate off-label clinical and economic information to decision makers? What is the level of influence of the dossier over formulary decisions?
- How do physicians consider off-label drug information when considering therapeutic options? What is their responsibility to share or restrict off-label information with patients? Does consideration of unapproved drug use threaten patient safety?
- What are the rights of patients to have access to truthful but unapproved information when they discuss drug treatment option benefits and risks with their health care professionals?
- What is the climate in Washington among policymakers and legislators to allow communication of off-label and economic data to prescribers, decision makers, and patients?

This seminar will review these evolving issues to consider the right of pharmaceutical companies, prescribers, and decision makers to freely communicate, discuss, and use evidence-based off-label data and information in population-based and patient-specific drug use decisions that impact patient care and economic outcomes.

Confirmed Seminar Podium Speakers

1. **FDA Regulatory Perspective** – FDA role in drug approvals and labeling, inclusion of economic information, FDAMA section 114, dangers of off-label communications, freedom of information – **Alan Bennett, Esq, former FDA attorney; counsel to the Medical Information Working Group**

2. **Pharma Regulatory Perspective** – Manufacturer exposure and opportunities with FDAMA section 114 update, recent court cases allowing off-label truthful evidence (Coronia and Amarin cases), and future implications on pharma promotional and MSL communications – **Mary Elizabeth Gatley, Esq, DLA Piper**

3. **Pharma Regulatory Perspective** – Manufacturer exposure and opportunities with FDAMA section 114 update, recent court cases allowing off-label truthful evidence (Coronia and Amarin cases), and future implications on pharma promotional and MSL communications

– **Mary Jo Carden, RPh, JD, Director of Regulatory Affairs, Academy of Managed Care Pharmacy**

4. **Prescriber perspective** - how should the label limit or support prescribing decisions? How do oncologists consider labeled data, compendia pathways and evidence, and off-label data to select oncology therapy **– John Geisler, MD, OB/GYN Oncologist**, **Cancer Treatment Centers of America**

5. **Pharmaceutical Manufacturer Perspective** - Information and promotion within and outside labeled indications; use of FDAMA 114 and dossiers; professional representative compliance vs MSL/medical information freedom to discuss off-label information – **Susan Spivey, PharmD, Medical Science Liaison, Gilead**

6. **Pharmaceutical Industry and Payer Communications; Impact of FDAMA section 114 –** how will the pharmaceutical industry evolve clinical and economic data communications to health care decision makers as well as prescribers? Will FDAMA section 114 offer protection that supports economic data communications? Who will drug value be communicated? – **Breanna Popelar, PharmD, MS, Xcenda**

7. **Patient Perspective** (optional) – patient access to insurance coverage information; what off-label information should be discussed between the physician and patient; patients' right to all truthful information; impact of PCORI; use of web resources – **Nicole Braccio, PharmD, Policy Director, National Patient Advocate Foundation**

Tentative Agenda

Day 1 - Saturday 4 March 2017			
Time	Session Tentative Title	Speaker	Speaker Affiliation
12:00pm - 12:50pm	Student registration		
12:50pm - 1:00pm	Seminar opening, agenda, announcements		
1:00pm - 1:50pm	1. FDA Reaction to Drug Information Evolution	Alan Bennett, Esq	Ropes & Gray
1:50pm - 2:40pm	2. Pharmaceutical Manufacturers Compliance and Off-Label Communications	Mary Elizabeth Gately, Esq	DLA Piper LLP
2:40pm - 3:30pm	3. Health Care Policy and Drug Information Communications	Mary Jo Carden, RPh, Esq, Director of Regulatory Affairs	Academy of Managed Care Pharmacy
3:30pm - 3:45pm	Break		
3:45pm - 4:35pm	4. Prescriber and Patient Use of Off-Label Information	John Geisler, MD, MS, OB/GYN oncologist	Cancer Treatment Centers of America
4:35pm - 5:45pm	Speaker Panel Discussion		
5:45pm - 7:00pm	Students in Assigned Group Case Study Presentation Work (classrooms)		
7:00pm - 9:00pm	Student - Faculty Buffet Dinner (on-site in HPNP foyer)		

Day 2 - Sunday 5 March 2017			
Time	**Session Tentative Title**	**Speaker**	**Speaker Affiliation**
7:00am - 8:00am	Continental breakfast (HPNP foyer)		
8:00am - 8:50am	5. Pharmaceutical Manufacturer Communications	Susan Spivey, PharmD, MS, MSc, Medical Science Liaison	Gilead Sciences
8:50am - 9:40am	6. Pharmaceutical industry drug information and value communications	Breanna Popelar, PharmD, MS	Xcenda
9:40am - 9:55am	Break		
9:55am - 10:45am	7. Patient Access to Health Care and Drug Information	Nicole Braccio, PharmD, Policy Director	National Patient Advocate Foundation
10:45am - 12:00pm	Speaker Panel Discussion		
12:00pm - 12:30pm	Lunch; students complete their presentations		
12:30pm - 2:00pm	Student groups present case study presentation to faculty (auditorium)		
2:00pm	Seminar conclusion and dismissal		