

From: Dana Reed-Kane [REDACTED]
Sent: Friday, February 06, 2009 1:23 AM
To: 'Matthew T. Slimp'; 'Deborah Pearce'
Cc: 'Richard B. Moon'; 'Diane Boomsma'; Sarah Dodge; [REDACTED] 'Gus Bassani';
'Jim Paoletti'
Subject: Suggested Modules (Components) for an FDA Inspection Guidance Plan for
Compounding Pharmacies and Their Employees

Importance: High

Dear Matt and Deborah,

On behalf of the IACP Board of Directors I would like to thank you for coming to Houston and presenting at our recent board meeting. After your presentation last Saturday, Sarah Dodge from IACP, and several board members/executive committee members began brainstorming projects that we would potentially like you to work on with the organization. You had mentioned in your presentation the fact that you had put together guidance for several of your clients on how to handle an FDA inspection. That guidance is what our members are asking for.

Sarah Dodge has put the following proposal together which explains what we are looking for and ideas that we all have come up with thus far. This is a work in progress and we would like input from you as well as any other executive committee member that may wish to augment our discussion.

After reviewing the information below, we would like you to submit your thoughts, a cost proposal and how you feel you could contribute to the project. We are very excited to hear what you think!

Thank you,

Dana Reed-Kane, Pharm.D., FIACP, FACA, NFPPhC, FCP
[REDACTED]



Suggested (Possible) Modules for (or Similar Title):

"Pharmacy Compliance and Pharmacy/Pharmacist Rights

Before, During and After an Inspection by the FDA -

What You Need To Know to Protect and Preserve Your Rights and Those of Your Patients"

To give everyone (including the Executive Committee) an overview of what seems to be the prevailing form of member education, I am including a recent survey of what association members (not IACP) polled by ASAE have been offered in terms of options for viewing their member services products:

- * Audiocassette (4 percent)
- * Handbooks/Other Written Guidance (30 percent)
- * CD-Rom (14 percent)
- * E-mail (10 percent)
- * Satellite broadcast (4 percent)
- * Teleconferencing (10 percent)
- * TeleWeb technology (11 percent)
- * Videotape (17 percent)

Some of our goals in pursuing the FDA Inspection/Constitutional Rights Seminar (for CCH) and member service materials, I believe, would be as follows:

How to meet member needs for convenient, cost-effective, certified continuing education programs?

IACP has certainly seen an increased interest in these programs and this has presented an opportunity for IACP to develop innovative and cost-effective continuing education programs to respond to member needs.

 The
Solution:

To maximize the member services and benefits we can provide to them at the best possible price and to yield the most effective product and helpful guidance to them and their staffs with a multi-tired product approach.

I believe that IACP can use both Internet Technology, the CCH meeting as a forum, CD-ROM technology and a traditional (brief) compliance manual to serve our members on this issue. IACP can provide convenient, cost effective educational information to more members through the suggestions outlined below.

Suggested Module Components/General Timeline:

March: IACP Begins to Develop Marketing Materials After Initial Overview of Suggested Material Development by Law Firm and Approval and/or Edit by Them & Executive Committee Approval of Process, Material and Financial Agreement;

March: Material Development Begins between IACP and Law Firm, with help from pharmacists and Executive Committee and Board, as needed;

May/April: As Conference approaches, some marketing materials are released with conference information highlighting law firm's upcoming presentation and general overview of material - and noted that seminar is for CCH attendees only;

June: Presentation (by Law firm) at IACP "Compounders on Capitol Hill" (CCH) Conference (June

13 - June 16, 2009 at the J.W.Marriott in Washington, D.C.) - Ideally a Power Point Presentation

with a Synopsis of the Major Points that Pharmacists and Their Technicians/Employees Need to

Know This presentation would also kick off the direct marketing of the member services products to be sold to members on the issue (and could be an addendum to this CE Course).

June (Would Like to Have Product Available by CCH for Distribution): Contents of Final Member Services Product(s)

1) Read-Only CD that pharmacists and their staffs can use to prepare for an inspection by the FDA (the CD should provide guidance on what to expected form the FDA and how to best be prepared for such an inspection, as well as how best to document each and every aspect of the inspection). Also, of equal, if not more importance, the CD should be specific and expand upon

what the Constitutional rights of the pharmacy/pharmacist are and what they are obligated to do; not obligated to do and what they should NOT do. A huge concern right now to the pharmacy community right now is the recent spate of FDA field agents who have overstepped their bounds and actually demanded to see patient files and asked pharmacists to sign affidavits

saying they would no longer sell certain products (which, unfortunately - these pharmacists, not

knowing their rights, signed under duress). Also, there should be guidance on when to contact one's attorney and when it is appropriate to end the visit by the FDA and when lines have been overstepped.

2) A Handbook (although not too cumbersome) that pharmacists' and their staffs' can use as a sort of "desk reference" before during or after an inspection by the FDA or to look up any last minute questions. It could also contain a helpful check-off list to review all key pre-visit items to have completed or available during the actual inspection.

3) Possibly (we could consider this for later, depending on how sales go) - we would charge a fee

for each participant - host a TeleWeb Virtual Seminar.

TeleWeb Virtual Seminars provide an efficient way to deliver conference content to a much wider audience of members. "Distance education" has enabled those members who would otherwise be unable to attend seminars in person (or who may not have ordered the product to benefit from conference and other IACP education programs.

Financial Aspects of Project:

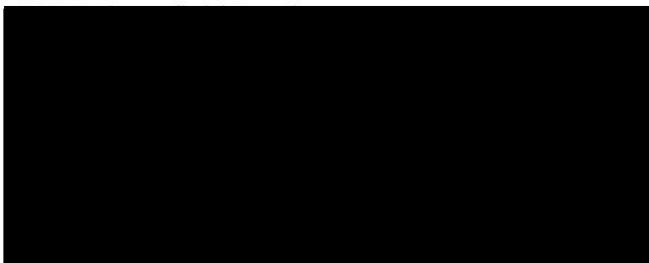
*Presentation at IACP "Compounders on Capitol Hill" (CCH) Conference (June 13 - June 16, 2009

*Production of Materials (Much of this would be at the Law Firm Contracted to do Project)

*IACP would help with marketing and PR on product (ordering, cost, etc.)

*IACP would need to agree to contract with law firm based upon a percentage of royalties (a percentage of the overall sales) on the product - thus, both IACP and the law firm would have a vested interest in sales from the product.

Sarah Ryan Dodge
Director of Government Affairs
International Academy of Compounding Pharmacists (IACP)



IACP Annual Meeting & Compounders on Capitol Hill
June 13-16, 2009
Register online today at <http://www.iacprx.org/CCH>

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