Maryland Board of Pharmacy
Public Board Meeting
Minutes

Date: January 16, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	**Commissioner/Treasurer**	✓		**5**	**2**
Chason, D.	**Commissioner**	✓		**7**	**0**
Finke, H.	**Commissioner**	✓		**7**	**0**
Gavgani, M. Z.	**Commissioner**	✓		**6**	**1**
Hammonds, S.	**Commissioner**	✓		**5**	**2**
Handelman, M.	**Commissioner**		✓	**6**	**1**
Israbian-Jamgochian, L.	**Commissioner**	✓		**6**	**1**
Matens, R.	**Commissioner**	✓		**4**	**3**
Souranis, M.	**Commissioner/President**	✓		**7**	**0**
St. Cyr, II, Z. W.	**Commissioner**	✓		**7**	**0**
Taylor, D.	**Commissioner**	✓		**7**	**0**
Taylor, R.	**Commissioner/Secretary**		✓	**5**	**2**
Board Counsel					
Bethman, L.	**Board Counsel**	✓		**7**	**0**
Felter, B.	**Staff Attorney**	✓		**6**	**1**
Board Staff					
Naesea, L.	**Executive Director**	✓		**7**	**0**
Wu, Y.	**Compliance Manager**	✓		**6**	**1**
Waddell, L.	**Licensing Manager**	✓		**1**	**0**
Gaither, P.	**Administration and Public Support Manager**	✓		**6**	**1**
Jeffers, A.	**Legislation/Regulations Manager**	✓		**7**	**0**
Johnson, J	**MIS Manager**	✓		**3**	**0**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. M. Souranis, Board President	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* 1. M. Souranis, President, called the Public Meeting to order at 9:40 a.m. 2. M. Souranis requested all meeting attendees to introduce themselves, to please sign the guest log and to indicate whether they would like continuing education credits before they leave the meeting. 3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. 4. M. Souranis reported that all handouts are to be returned by attendees when they leave the meeting. 5. Review and approval of December 19, 2012 public board meeting minutes. Amended as follows: Pages 1 and 4, strike James, D. as acting Licensing Manager and replace with Waddell, L. Licensing Manager.	Motion to accept minutes as amended made by D. Chason. Motion was seconded by M. Gavgani.	Motion was approved.

II. Executive Director's Report	A. Executive Director, L. Naesea	**Operations Update** – L. Naesea announced that the Board is pleased to welcome LaToya Waddell as the Board's new Licensing Manager. With the recent hiring of John Johnson as the Board's MIS Manager, the Board has now completed its hiring for all of the Board's manager positions. Operations have dramatically improved and John Johnson will go into more detail on Operations in his MIS presentation.		

		Meeting Updates: • L. Naesea reported that she, Y. Wu, B. Felter and A. Jeffers attended a meeting in mid-December between representatives from most of the country's pharmacy boards and the FDA to discuss sterile compounding. NABP prepared a summary of the meeting which is attached hereto and made a part of these minutes as "Attachment No. 1." Definitions for compounding pharmacies and manufacturers need to be clearly provided in federal and state statutes. Maryland has these terms defined, however many state statutes do not. L Naesea reported that the FDA definition is somewhat ambiguous because it considers compounders of non-patient-specific prescription drugs to be "non-traditional" pharmacies, whereas Maryland and most other state board consider these entities to be manufacturers that shold be regulted by the FDA. . • L. Naesea, R. Taylor and A. Jeffers attended a meeting with Secretary Scharfstein to discuss concerns about sterile compounding. (See detail in her Legislation-Regulations section.) • L. Naesea and A. Jeffers also attended a meeting with hospital pharmacy representatives conducted by Delegate Morhaim to discuss wholesale distribution and drug shortages. (See Legislation-Regulations section for details.) • L. Naesea introduced and welcomed the Board's latest intern from the University of Maryland (Baltimore) School of Pharmacy, Darci Eubank. Ms. Eubank's rotation at the Board started January 15, 2013 and will she be with the Board for five weeks.		

B. Administration & Public Support	Administration & Public Support Manager, P. Gaither	**1. Personnel Updates:** • John Bozek has been hired as the Board's new Computer Network Specialist, effective January 9, 2013 • One vacancy remains for the inspector position, which has been posted. Receipt of applications closed on January 13, 2013. The Board is waiting on a list of names for interviews and anticipates filling the position in four to six weeks. . • LaToya Waddell has been selected as the Board's Licensing Manager. Ms. Waddell's former position as Licensing Specialist is vacant and the Board is actively recruiting for that position. Current staff will have an opportunity to apply for the postion before recruiting externally. • The contract for temporary staff in the Board's Licensing Unit expired. A freeze exemption has been approved to hire a new individual in that position and recruitment has begun. • The Board is working to amend its budget to recruit and hire a pharmacist. **2. Contracts and Procurement** • See MIS Unit Section.		
C. MIS	J. Johnson, MIS Manager	1. MLO system and application updates.		

		• The Board is still determining software needs before a new contract can be finalized with State Archives for providing back-up support for the Board's automated systems. • Issues experienced with the the new MLO system include licensees having an ability to renew on-line but not being able to view or print the confirmation page. The Board's payment processing center, does confirm that payment has been received to Board staff. The Board is working with System Automation to resolve this issue. • J. Johnson reported that he and L. Naesea will be meeting with SA next week to discuss the response time from SA when issues are submitted by the Board.		
D. Licensing	L. Waddell, Licensing Manager	Monthly Statistics for October and December, 2012. Pharmacists: • New Applications – 45 • Renewals – 320 • Total – 9229 Pharmacists Administer Vaccinations: • New Applications – 24 • Renewals – 2 • Total - 2135 Technicians: • New Applications – 128 • Renewals – 210 • Total - 8197 Student Technicians • New Applications – 22 • Renewals – 28 • Total - 490		

		Pharmacies: • New Applications – 7 • Renewals – 0 • Total - 1841 Distributors: • New Applications – 20 • Renewals – 0 • Total – 996		
E. Compliance	Y. Wu, Manager Gil Cohen, PEAC	1. Monthly Statistics for December, 2012 <u>Complaints & Investigations</u>: New - 15 Resolved – 54 Final disciplinary actions taken –13 Reversal – 0 Summary Actions Taken – 0 <u>Inspections:</u> 70 Annual - 57 Opening - 3 Relocation - 3 Closing - 5 (performed by the Division of Drug Control) PEAC Update – Commissioner D. Chason. reported that a PEAC representative was unable to attend the meeting but had submitted a one page summary of a grant received. The written report is attached hereto and made a part of these minutes as "Attachment No. 2."		
F. Legislation & Regulations	A. Jeffers	**<u>MEETINGS:</u>** **1) Durable Medical Equipment Provider Task Force** First meeting was held January 8, 2013. A.Jeffers reported that at the initial meeting of the DME Provider Task Force the the Board Chairs of the Task Force determined that it may be an unreasonable burden to require DME and device		

		providers that do not dispense drugs to have a pharmacist on staff. The Board was asked to consider proposing legislation that would waive the pharmacist requirement for dispensers of prescription devices and DME providers who do not dispense drugs. Accreditation from a Board-approved entity and/or a requirement for certain allied health professionals depending on the type of devices dispensed could also be required. (For example, for C-Pap providers, require a respiratory therapist.) **The Board accepted the suggestion and will identify a sponsor for the proposed legislation. An emergency effective date will also be requested.** **2) Meeting with the Secretary – to address sterile compounding concerns** Board representatives, L. Naesea, R. Taylor, and Anna Jeffers, met with Secretary Sharfstein, Deputy Secretary for Public Health, Dr. Herrera, and Patrick Dooley (Sec. Sharftein's Assistant) to discuss ways that the Board of Pharmacy could increase oversight of compounding pharmacies that dispense to Maryland patients. The Secretary asked the Board to submit a comprehensive proposal that would include what the Board has in place now and what laws and regulations could be strengthened to increase oversight and ensure safe compounding in Maryland. A draft proposal and cover letter was presented for approval at the Board Meeting. **The Board approved the letter (below) and proposal with a revision that would also propose Board oversight of any person performing a pharmacy practice in Maryland.** Dear Secretary Sharfstein: Thank you for taking the time to meet with Maryland Board of Pharmacy (the Board) representatives about mutual concerns related to sterile compounding issues and the need to ensure that State monitoring efforts are maximized to assure greater		

		protection for Maryland patients. Compounding pharmaceutical products pursuant to a prescription or drug order is one of many activities that constitute the practice of pharmacy. Thus, it is vitally important that persons engaged in sterile compounding, and any pharmacy practice, be monitored by the regulatory board responsible for ensuring safe pharmacy practice (i.e., in this State, the Maryland Board of Pharmacy). The recent national outbreak of meningitis, allegedly caused by NECC pharmacy's failure to adhere to required sterile compounding standards under USP <797> and its home state's rules, as well as inadequate monitoring in that home state, was a cautionary tale for all federal and state bodies that regulate sterile compounding. In Maryland, it provided an additional opportunity for the Board to review current regulatory and monitoring measures for all persons and entities engaged in any form of pharmacy practice, determine where there are gaps in oversight, and develop and recommend a plan to address all identified gaps. The attached proposal is submitted for your immediate consideration and support of recommendations to address gaps in sterile compounding oversight. In light of the time limitations the Board will submit within a week, a second proposal to discuss gaps identified in monitoring all persons and entities engaged in any form of pharmacy practice, including physicians, dentist and podiatrist who dispense prescription drugs to their patients, and offer recommendations for addressing those gaps. The current proposal is divided into five sections. Section I describes current State sterile compounding monitoring efforts; Section II discusses Board-identified gaps in State regulating and monitoring efforts; Section III provides Board recommendations for addressing the identified gaps; Section IV provides timelines for implementing legislative initiatives; and Section V provides the proposal conclusion. Though not perfect, the Board presently administers a fairly strong regulatory and monitoring system for sterile compounding		

		pharmacies; however, there does not appear to be a similar set of State requirements or structured monitoring in place that assures safe practice by non-pharmacy practitioners (physicians, dentists, podiatrist, and veterinarians) who prepare sterile compounding products. Thus, some proposal recommendations may be implemented immediately, while others require actions that may take up to a year and a half to plan and fully implement. The latter will assure long-term, comprehensive protection for patients that use sterile compounded products. The most important and ultimate goal is to consolidate regulatory oversight and monitoring of any and all persons engaged in sterile compounding (pharmacy or practitioner) licensed by a Maryland regulatory board, under a single authority. This recommendation is made for several reasons, including building a new system for monitoring sterile compounding practitioners on the existing foundation established by the Board for regulating and monitoring sterile compounding pharmacies. Also, fewer budgetary, personnel and training resources would be required to create the new area of monitoring, since the Board is thoroughly familiar with USP <797> Standards and has enforced adherence to USP <797> Standards since 2008. In order to meet this goal, extensive research would be required to review existing the statutes and regulations of the affected practitioners' respective licensing boards to assure that any newly proposed disciplinary proceedings or actions would not conflict with existing requirements. Also, an assessment of the number of practitioners that perform sterile compounding would need to be made, and additional equipment acquired. A determination of the appropriate number of inspectors to be recruited and the types of additional training would need to be considered as well. The Board therefore recommends the introduction of a legislative proposal during the current legislative session that contains four mandates: A. Strengthen the Board of Pharmacy's existing statutory authority		

		by implementing recommended short-term statutory changes for compounding pharmacies (See Section IIIA); B. Strengthen the protection of patients currently at–risk by implementing the short-term actions recommended for compounding practitioners (See Section IIIB); and C. Strengthen statutory/regulatory oversight and monitoring of all entities that perform sterile compounding for Maryland patients and animals by granting jurisdiction to the Board over all sterile compounding; and D. Authorize the Board to form a Sterile Compounding Oversight Workgroup that will: 1. Recommend standards to be met by all sterile compounders in Maryland before the Board issues a sterile compounding permit authorizing them to perform sterile compounding for Maryland patients; 2. Research existing requirements and State disciplinary rules in order to develop appropriate disciplinary responses when those standards are violated; and 3. Determine resources required for the Board to monitor sterile compounders in Maryland and ensure compliance with the new standards, including but not limited to personnel, equipment and training. Anticipating your committed support of the proposed 2013 legislation and the successful completion of the short-term steps outlined in the attached proposal, the Board feels that the ultimate goal could initiated by July 2014. Thank you again for your attention and interest in this important issue. Should you have questions or additional concerns, please feel free to contact me [L. Naesea] or Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794. STEPHEN PLEASE MAKE THE DELETED PROPOSAL ANOTHER ATTACHMENT, RATHER THAN PUTTING IT DIRECTLY IN THE MINUTES		

		3) Drug Shortages Meeting – Delegate Morhaim A. Jeffers reported that Del. Morhaim brought together wholesale distributor stakeholders on January 10th to discuss ways to prevent drug shortages and also to prevent price inflation of prescription drugs. He asked the Board to do three things: A) Submit the wholesale distributor regulatory proposal as an Emergency so that the new definition for "retail pharmacy" which includes both retail and waiver pharmacies and the 5% rule would apply as soon as possible. Ms. Jeffers submitted that proposal emergency on January 15, 2013. B) Require applicants for pharmacy and wholesale distributor permits to disclose if they are both a pharmacy and a wholesale distributor. This can be accomplished by amending both applications. C) Restrict wholesale distribution by pharmacies licensed by the Board to any person, except other pharmacy permit holders, reverse distributors, or pharmacy warehouses as defined by the Maryland Pharmacy Act. The Practice Committee made this recommendation in December. Since the Federal Legislation did not pass, the Board was asked if it wanted to seek the statutory change. (Del. Morhaim will sponsor) Delegate Morhaim also suggested that a consortium among the hospitals be created to share medications that might be in surplus or needed for emergency reasons. **The Board approved working with Delegate Morhaim to have this legislation introduced. It was suggested to add practitioners as another exception for pharmacy distribution.** **4) Ratification of letter sent to Legislative Committee Chairs, Carter-Conway and Hammen providing the Board's recommendations for reporting requirements for compounding pharmacies and the necessity for annual**		

		inspections of all dispensers. AGAIN STEPHEN, PLEAE MAKE THIS LETTER ANOTHER ATTACHMENT **The Board ratified the above letter.** **LEGISLATION:** **HB 1 Criminal Law – Cannabimimetic Agents – Prohibition** Hearing 1/22/13 **hb0001f** The Board voted to submit a Letter of Information that noted that the definition of "cannabimimetic Agents" in HB 1 does not include an exception for any drug that has been approved by the U.S. Food and Drug Administration (FDA) as in the definition of "synthetic cannabinoid" in SB 109 Criminal Law – Controlled Dangerous Substances – Research – Synthetic Cannabinoids. **HB 59 Dedicated State Funds Protection Acthb0059f** The Board voted to submit a Letter of Support **SB 44 Occupational and Professional Licensing – Military Training and Military Spouses** **sb0044f** The Board voted to join a joint position paper with other health occuaptions boards to oppose. **SB 94 Child Abuse and Neglect - Notice and Reporting Requirements, Disclosure, and Task Force**		

		sb0094fSB 63 - Boards Letter of Support (2012) The Board voted to join a Letter of Support with the other health occupation boards **New legislation introduced after January 11, 2013 will be emailed before the meeting.** **SB 109 Criminal Law - Controlled Dangerous Substances - Research - Synthetic Cannabinoids** In 2012 the Board submitted a Letter of Support. (Failed) The Board voted to submit a Letter of Information that noted that the definition of "synthetic cannabinoids" in SB 109 includes an exception for any drug that has been approved by the U.S. Food and Drug Administration (FDA). HB 1 Criminal Law – Cannabimimetic Agents – Prohibition, did not include this exception. **New Board of Pharmacy Legislation:** **Board approval requested for legislation which would restrict wholesale distribution by pharmacies to any person, except other pharmacy permit holders, reverse distributors, or pharmacy warehouses as defined by the Maryland Pharmacy Act.** **Delegate Morhaim offered to sponsor for the Board.** **See section on Drug Shortages above.** **REGULATIONS:** **10.34.03 – Inpatient Institutional Pharmacies** Released for informal comment 12/04/12 – 1/14/13. To be addressed at January 23, 2013 Practice Committee. **10.34.06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment** Published in the Md. R. 12/28/12 with comment period through		

		1/28/13. **10.34.11 - Disciplinary Monetary Penalties, and Civil Fines** Effective Date of 12/24/12. **10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.** Proposal waiting for the Secretary's sign-off. The Board approved adding in DDC to also receive notice of a permit holder closing. **10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors** This proposal was submitted Emergency on January 14, 2013 at Delegate Morhaim's request. Notification of dual licensure could be added to the applications now. **10.34.23 Pharmacutical Services to Patients in Comprehensive Care Facilities** Released for informal comment 12/04/12 – 1/14/13. To be addressed at January 23, 2013 Practice Committee. **10.34.29 – Drug Therapy Management** Proposal anticipated to be published 1/25/13 with comment period through 2/25/13. **10.34.36 – Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes** Proposal anticipated to be published 1/25/13 with comment period through 2/25/13. FYI – COMAR 10.47.07 PDMP in effect as of January 7, 2013. Actual implementation will not occur until late summer.		
III. Committee Reports	H. Finke, Chair,	No report this month as the Practice Committee did not meet since the December, 2012 public board meeting.		

A. Practice Committee				
B. Licensing Committee	D. Chason Chair,	1) Review of Pharmacist Applications: None 2) Review of Pharmacy Technician Applications: None 3) Review of Distributor Applications: None 4) Review of Pharmacy Technicians Training Programs: None 5) New Business: • Tracy Samon c/o Blackstone Medical Services - Blackstone Medical Services would like to know what kind of licensure that is required for the services they provide. The Company services the sleep-disordered breathing market. They ship the Sleep Device to the patient's home; the patient performs the test and ships it back. Recommendation is to inform Ms. Samon that if it requires a prescription then they will need to be licensed as a pharmacy meeting the requirement of having a MD licensed pharmacist on staff and to inform her of the existence of the Durable Medical Equipment Task Force. • Mariela Cebic c/o Sunmed LLC – Questions the validity of expiration date of Distributor permit. Recommendation is to inform Ms. Cebic that the Board cannot approve a permit for a period of longer than two years based on statutory MD law.	Recommendation by Licensing Committee to: 1) inform Ms. Samon that if it requires a prescription Blackstone will need to be licensed as a pharmacy meeting the requirement of having a MD licensed pharmacist on staff ; and 2) inform her of the existence of the Durable Medical Equipment Task Force Recommendation was seconded by D. Taylor. Recommendation is to inform Ms. Cebic that the Board cannot approve a permit for a period of longer than two years based on statutory MD law. Recommendation was seconded by D. Taylor.	Recommenda-tion was approved. Recommenda-tion was approved.

C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update: • The Fall Newsletter has been sent out and the Committee is currently working on the Winter Newsletter. • The Public Relations Committee will be instituting a series of quarterly public service announcements. Print ads, newspapers, magazines as well as on-line ads will be utilized. The first announcement will focus on the flu epidemic and that vaccinations are available. Other messages the Committee is considering are the "pharmacist as a resource" and flu vaccination by pharmacists which the Committee would consider as a public service announcement in the fall. • The Center for Disease Control issued a letter to pharmacists dated January 15, 2013 titled 2012-2013 Influenza Season – Information for Pharmacists. This letter will be posted to the Board's public website. • The Public Relations Committee is still exploring off-site locations at which to host one public board meeting in 2013. The region will be the eastern shore and the date will be October 16, 2013.		
D. Disciplinary	L. Israbian-Jamgochian, Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	D. Taylor, Chair	Emergency Preparedness Task Force Update : • DHMH meeting on next CDC evaluation of State of Maryland Emergency Preparedness Plan and the Board of Pharmacy was not invited to the evaluation this year. Commissioner Taylor is looking into that fact to see if it was an oversight or not. • The number of volunteers has dropped significantly from 600 to approximately 130. Commissioner Taylor seeks the Board approval to send letter to all of the volunteers who are not	Motion by D. Taylor for Board to approve Emergency Preparedness	Motion was approved.

		registered with the new MD system to ask them to consider re-signing as volunteers with the new system. The letter would go out under the Board's Task Force and would be sent out by the Department of Health and Mental Hygiene.	Task Force sending letter to previously registered volunteers asking that they consider volunteering again and registering under the new MD system. Motion was seconded by R. Matens.	
IV. Other Business & FYI	M. Souranis, President	No Other business to report this month.		
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 11:50 p.m. At 12:49p.m. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 1:07 P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion by R. Matens, to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by D. Taylor.	Motion was approved.

Attachment No. 1: National Association of Boards of Pharmacy Summary of Meeting with FDA regarding Sterile Compounding:

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: December 20, 2012
RE: FDA Meeting Follow-up

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Our thanks to the state boards of pharmacy that participated in the FDA Intergovernmental Meeting yesterday and presented critical information from the states' perspectives. The dialogue between the states and FDA was beneficial and will be even more beneficial if the FDA and the Commissioner accept the feedback and incorporate your recommendations into their present and future proposals and testimony.

NABP will be sending a letter to Commissioner outlining the primary recommendations of the states from yesterday's meeting and requesting that the Commissioner incorporate these recommendations into the FDA's activities and proposals. In listening to the summary reports, we identified some initial points for affirmation with the Commissioner and FDA that follow:

1. Definitions for compounding and manufacturing must be established in federal and state statutes and regulations that are concise and uniform. The basis for the distinction between these two activities is patient specificity. Patient specific activities are defined as compounding and non-patient specific activities are considered manufacturing. Although there can be a consideration of exceptions and a continuum, the continuum should be defined within the manufacturing sector and fall under the authority of the FDA with support from the states as requested and as qualified to do so.
2. Bidirectional communication must occur between FDA and the states. This is critical to the inspection of compounding pharmacies and manufacturers and especially necessary when regulatory or disciplinary actions are initiated, pursued, or finalized with pharmacies and manufacturers. FDA's participation in regional meetings and discussions and increased communication vehicles between the FDA and states are additional, important requests from the states.
3. Resources and special training in key areas are needed by the states to effectively assume the new responsibilities discussed and to assist the FDA with the challenges currently being faced to develop the needed regulatory structure.
4. The states desperately need a clarification of the FDA's registration of a manufacturer. Entities involved in the manufacture of drug products are indicating to the states and NABP that such registration with the FDA entitles them to manufacture any unapproved,

not available commercially, or shortage drug product listed on the FDA's website. Information provided by an FDA staff person at the meeting yesterday, and in the research NABP has conducted, indicate that this is not true and that all manufacturers must hold an ANDA or NDA for every product that they manufacture.
5. The concept of non-traditional compounding is not defined in state statutes and is not something that the states will support as a third tier of drug production. We will request that the Commissioner not pursue establishing this third tier of activity.

We are reaching out to you and specifically the person who represented your state, to review the list above and to make any corrections or additions. It was evident at the meeting that not all states agreed on every detail of the items discussed at the meeting but there was overwhelming consensus for the points noted above.
NABP wants to continue to ensure that the states are heard throughout the discussion of compounding and manufacturing and that your recommendations are not lost amidst the clamor or other groups or interests. It is our firm belief that the states are integral to the solution of this problem and that primary impetus for this crisis are the drug shortages and the environment that fostered the rise of manufacturers operating under the guise of compounding pharmacies. The need to alleviate drug shortages and resulting pressures from a myriad of stakeholders certainly contributed to the approaches that were advanced, or not advanced, in the regulation of these entities. These issues must be addressed as the states indicated at yesterday's meeting and the problem misdirected to legitimate compounding regulated by the states. Nor should solutions focus on changing the authority of the states in regard to legitimate compounding when the problem and solutions lie beyond this area and draw heavily from drug shortages and manufacturing activities.
Thanks for your input and leadership!
cc: NABP Executive Committee

Attachment No. 2: PEAC Summary of Grant:

On December 1, 2012, The Pharmacists' Education and Advocacy Council was granted funding by the Open Society Institute for a project of community education, with the aim to reduce the stigma of addiction by educating the general public and key community leaders in Maryland who are in the position to affect change within their communities.
The first step in this process will be to hire a project manager, and interviews have begun as we have received 20 possible applicants. This project director will produce a program and will interview healthcare professionals, who will deliver the message. These professionals will be trained to deliver this educational program based on the signs and symptoms, the recovery potential in the early stages of the disease, and provide the tools necessary to intervene effectively.
The major goal of the project is to increase the desire for intervention early in the course of the illness.
Because this is a community based program, the next announcement will be a joint effort with a major teaching institution in Maryland. We are proud to bring our Pharmacy profession to the general public in this manner.

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