

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, March 11, 2009, 9:00 a.m., at the Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Helen Caulton-Harris, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman (arrived at 9:35 a.m.), and Dr. Michael Wong. Absent Members were: Mr. Denis Leary, Dr. Alan C. Woodward and Dr. Barry Zuckerman. Also in attendance was Attorney Donna Levin, DPH General Counsel.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

"LEHMAN PATIENT SAFETY AWARD", BY NANCY RIDLEY, DIRECTOR, BETSY LEHMAN CENTER FOR PATIENT SAFETY AND MEDICAL ERROR REDUCTION:

Ms. Nancy Ridley, presented the Lehman Patient Safety Award jointly to the Massachusetts Hospital Association (MHA) and the Massachusetts Organization of Nurse Executives (MONE) for demonstrating commitment to public transparency and for the active involvement of patients in quality and safety initiatives. Ms. Karen Nelson, MPA, RW, Senior Vice President, of Massachusetts Hospital Association (MHA) accepted the award on behalf of MHA. She said in part, "...I do have to remark on one of the review criteria included aside from patient safety and transparency which is organizational culture and this culture change had to take place in every single hospital, almost one hundred hospitals participated in Patients First...It took a great deal of persistence and effort for hospitals to get to the point of acknowledging their own accountability for patient safety. On behalf of all the hospitals, I am grateful and proud of this

award and it could not have happened without the very tight partnership with the Massachusetts Organization of Nurse Executives." Ms. Sharon Gale, MS, RW, Executive Director, Massachusetts Organization of Nurse Executives (MONE) accepted the award on behalf of MONE. She said, "I want to add my thanks to everyone, especially to the Lehman Center and to say that Patients First has been an outstanding example of collaboration and commitment that has been sustained over a long period of time, several years, which is quite remarkable, and it continues to strengthen and grow, and I think it is a good example of how actions speak louder than words. It is very good to be part of that initiative and I thank all of you for this very nice honor."

Chair Auerbach thanked Nancy Ridley and her staff for their work at the Betsy Lehman Center and noted that the Lehman Center work has provided a strong foundation for the work of the Public Health Council related to hospital associated infections data.

FINAL REGULATIONS: REQUEST FOR FINAL PROMULGATION OF REGULATIONS 105 CMR 970.000, PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT BY MELISSA LOPES, DEPUTY GENERAL COUNSEL, OFFICE OF THE GENERAL COUNSEL:

Chair Auerbach noted how the Public Health Council Members worked closely with the State Ethics Commission and underwent a rigorous review in order to determine which PHC members had any conflicts of interest that would preclude them from discussion and voting on the regulations. He said in part, "It was determined that three of the 15 members had financial conflicts of interest and therefore, can't participate in the discussion or vote on the regulation and wouldn't be counted towards a quorum. These financial interests included but aren't limited to such things as stock ownership or benefits provided through institutional grants and those members are: Dr. Michèle David, Dr. Michael Wong, and Dr. Zuckerman." Chair Auerbach further noted that "seven PHC Members have what is called a potential appearance of conflict of interest which means there is no financial conflict but there might be circumstances that might make it

appear that there is a conflict including past advocacy on the authorizing legislation for the regulations, litigation-related activities, or employer receipts of grants. The Ethics commission determined that these members can participate fully in the discussion and vote on these regulations. These members are: Mr. Harold Cox, Dr. John Cunningham, Dr. Muriel Gillick, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Dr. Meredith Rosenthal and Mr. Albert Sherman. The Ethics Commission determined further that four of the Council Members had neither a conflict or the appearance of a conflict and those Members are: Mr. José Rafael Rivera, Mr. Paul Lanzikos, Ms. Helen Caulton-Harris, myself [Chair John Auerbach] and Dr. Alan Woodward.”

Attorney Melissa Lopes presented the Pharmaceutical and Medical Device Manufacturer Conduct regulations to the Council for final action. Attorney Lopes noted that the regulations were drafted pursuant to Chapter 111N of Chapter 305 of the Acts of 2008 and said in part, “...These regulations seek to identify and minimize potential conflicts of interest in the industry/health care practitioner relationship, to ensure transparency around industry payments to health care practitioners without compromising the legitimate and beneficial industry/health care practitioner interactions, and also to place pharmaceutical and medical device manufacturers on equal footing with respect to the requirements of Chapter 111N...”

Attorney Lopes noted that there are three main components of the Law: (1) The Code of Conduct which restricts certain marketing activities by industry actors, and sets the Pharma and AdvaMED Voluntary Codes as the floor; (2) a compliance program that is enforced on these manufacturers; and (3) a public disclosure requirement.

Regarding public hearings, Attorney Lopes mentioned that two public hearings were held in January in Boston and in Worcester. “Over 150 people attended in Boston and about 80 people attended in Worcester and the comment period ended on January 19, 2009. Over 109 written comments were received in addition to the oral testimony at the hearings. Comments were received from consumers and the industry as well as those indirectly affected by the

regulations such as the visitor industry, consumer, and charitable organizations. Some of the representatives from the consumer side included The Massachusetts Prescription Reform Coalition; Health Care for All; AARP and Senators Richard Moore and Mark Montigny. Comments from the industry perspective included: Pharma, the industry's trade group for the pharmaceutical manufacturers; AdvaMED, an industry trade group for medical device manufacturers; MassMedic, a local medical device manufacturers trade group; and individual manufacturers, such as Astra Zeneca, Wyeth, Boston Scientific, etc.

Attorney Lopes indicated, "...We clarified the draft regulations in a number of places. We had to clarify certain definitions to make sure that it reflected actual research and development of drugs, and how scientists work here in Massachusetts. We made sure that terms were used consistently throughout the regulations and that commas were placed so as not to mislead people as to the true intent or meaning of the regulations. We made substantive changes with three goals in mind. The first of these was to limit industry interactions with health care practitioners that may influence the prescribing patterns and/or adversely affect the care patients receive here in Massachusetts. The second of these goals was to increase transparency surrounding industry payments to cover recipients under the regulations, and the third was to not unduly restrict beneficial industry interactions with health care practitioners or other covered recipients that increase access to advances in the diagnosis, treatment and prevention of disease."

Attorney Lopes noted that Massachusetts is the only state to require adoption of and compliance with, a state-authored code of conduct for pharmaceutical and medical device manufacturers; it is the only state to prohibit certain payments to health care practitioners by both pharmaceutical and medical device manufacturers; it is the only state to require disclosures by medical device manufacturers; and one of only two states to make disclosure data part of the public record.

Some of the changes made to the regulations as a result of comments are:

- changed the definition of pharmaceutical and medical device manufacturer to apply to a broader array of pharmaceutical medical device manufacturers and distributors here in Massachusetts;
- limited the influence of marketing and health care consulting agreements by adding an additional limitation that a health care practitioner may be hired as a consultant, as long as the consultancy does not amount to purely serving as a sales representative for the company;
- eliminated the exemption for health care practitioners in training;
- limited exemptions for genuine research in clinical trials to research that is not sponsored or conducted by the sales and marketing departments of a pharmaceutical or medical device manufacturer and doesn't have marketing or product promotion or advertising as its primary purpose;
- clarified that under the code of conduct provisions, manufacturers need not restrict payments provided to full time employees or board members even if the employee is a health care practitioner also not subject to disclosure;
- clarified that medical device manufacturers may provide demonstration and evaluation units to health care practitioners for their own use;
- clarified for medical and device manufacturers' that genuine research and clinical trials does not always include human subjects;
- clarified for charitable organizations that donations of drugs and devices in the event of a Public Health crisis, natural disaster and other charitable need are allowed with limitations that the donations are not offered simply to increase the marketing of a certain drug or for promoting the prescribing of a certain drug, or device and these are not subject to disclosure;
- clarified that conferences, meetings and meals in conjunction with CMEs could be conducted at hotels and convention centers not just hospital settings;
- clarified that the \$50.00 threshold will be applied on a per person transaction basis;

- provided a new exemption from disclosure for prescription drugs provided at no cost to covered recipients solely and exclusively for use by patients;
- provided exemption to the disclosure requirements for the provision of confidential rebates and discounts by pharmaceutical and medical device manufacturers.

With regard to those items subject to disclosure Attorney Lopes said, "There have been a number of additional exemptions from disclosure, but I just want to assure everyone that the regulations still ensure and require broad transparency with regards to industry payments. For example, the proposed regulations, as amended, require disclosure of any advertising promotion or other activity that is intended or used to promote products or affect prescribing patterns by health care practitioners. We require disclosure of any product education or training that has marketing or product promotion, or advertising as its purpose. Charitable donations to hospitals, universities and 501 (C) (3) s will still be subject to disclosure. The only exemption is for in-kind items, charitable donations, and sponsorship of CME third-party conferences, scientific or professional meetings will still be subject to disclosure, as well as consulting payments in conjunction with marketing-based research, and any other economic benefit with a value of fifty dollars or more directed at and benefiting a covered recipient."

Attorney Lopes noted that there will be an accessible and comprehensive web site on disclosures, "Each annual disclosure report filed by manufacturers will be made publicly available and easily searchable on a web site established by the Department and the Department is committed to making this information accessible to a diverse population of health care practitioners and patients."

Attorney Lopes noted further that there are enforcement and penalties provisions in these revised regulations for the Department and the State Attorney General and for the implementation dates of the regulations: "On July 1, 2009, companies will have to come into compliance with the Code of Conduct. They will have to submit the information in Section 970.005 of the regulations, which is the

Compliance Information. They have to disclose to the Department their compliance Officer and give the Department some information on how they plan to make the initial payment of the \$2,000 annual fee. On July 1, 2010, the Department is requiring submission of the first disclosure Reports by pharmaceutical and medical device manufacturers and distributors, and that they will cover the period from July 1, 2009 to December 31, 2009..."

In closing, Attorney Lopes stated, "The Department of Public Health, with the advice of the Executive Office of Health and Human Services and the Office of the Attorney General, engaged in an in depth review of the regulations and the various comments received during the hearing and comment period, and the interest of all impacted parties, and these proposed regulations, with the changes that are reflected in them, demonstrate this balanced approach that we have sought to sort of limit the undo influence of commercial interests, but also promote or not impede beneficial industry/health care practitioner interactions that benefit health care consumers here in Massachusetts. We ask that you approve these final regulations as proposed."

Discussion followed by the Council (please see verbatim transcript for full discussion). Mr. Lanzikos noted that he attended one of the public hearings and the fact that some folks said the regulations go too far and others say they didn't go far enough means that the Department is probably where it should be. It was clarified that mugs and pens and things of that nature are prohibited. Mr. Lanzikos made the suggestion that on the proposed web site, "in addition to the identification of the company, the name of the firm, that you add two searchable fields, one that includes the name of the commonly used products. For instance, include the names of the commonly used trade names as opposed to the scientific names, as well as some reasonable rational aggregation for cardiac drugs or diagnostic equipment etc." Chair Auerbach noted that this suggestion will be brought before the vendor as we develop a contract to develop the web site which will be done in Paul Dreyer's bureau. Mr. Lanzikos further suggested that the trade groups who presented testimony on the regulations may be able to distribute a communication to their

membership on the need for companies to adhere to these regulations. Mr. Lanzikos asked for clarification on the charitable contributions to 501 (c) (3) s and in-kind donations. Attorney Melissa Lopes noted in part, "that the reason for exempting the disclosure of in-kind products is because it is usually only in response to a particular need or occurrence. However, when a pharmaceutical or medical device manufacturer makes a donation to a 501 (c) (3), that 501 (c) (3) may have very direct connections with certain health care practitioners, and perhaps we want that to be disclosed so that we can see whether or not they are making contributions just to try to influence prescribing behavior." Attorney Lopes said maybe they should change the language to "in-kind products for charity care" to make it clearer in the regulations.

Dr. Rosenthal asked for clarification on giving free samples of medication to patients. Attorney Lopes said "free samples may be given out under this statute and under the regulations and they are exempt from disclosure under the regulations." Ms. Lucilia Prates Ramos had concerns around health care practitioners' prescriber data being mined for marketing purposes; and that the original intent was for the \$50.00 to be aggregate like in the Minnesota Law not per individual. Attorney Lopes responded in part, "...These provisions are from the Pharmaceutical or Medical Device Voluntary codes, the regulations protect health care practitioners from having to provide this information by saying that pharmaceutical or medical device manufacturers must give health care practitioners the opportunity to request that prescriber data not be mined and the fifty dollar interpretation was based on how the statute was written and the Department wanted to clarify for people that it was for any individual transaction."

Dr. Muriel Gillick had a concern with the new exemption for free samples of prescription drugs, "It seems to me that that is indeed an example of an attempt to unduly influence prescribing patterns of physicians...The purpose of getting free samples is to try to ensure that the patient will, over the long run, go on that particular drug. I think that is not beneficial to patients to be taking Drug A over the long run if Drug B would be at least as effective and quite likely less

expensive. And the second argument about its ostensibly being beneficial to patients to get free samples was that it would save them some up front costs. There may be co-pays or payments that they might make early on while we are figuring out what medicine to take for a particular disorder; and, with all due respect, I would suggest that worrying about up front costs is a little bit like luring people to buy a house that they can't afford by making sure that the down payment is very low. My proposal would be that the regulations as you have proposed them to us are magnificent, but I would get rid of that exemption that you introduced de novo for free prescription drugs." Discussion continued. Ms. Helen Caulton-Harris expressed her concern for people who could not afford the medications.

One of the questions Mr. Harold Cox asked was does the Department plan on reviewing the data for impact on potentially intended as well as unintended impacts or effects of the data. Chair Auerbach responded in part, "It is a sub-regulatory recommendation with regard to how programmatically we plan to use the information...I am looking at Paul and we are both nodding that we can take your recommendation that the data be analyzed from the perspective that you are suggesting and that we report back to the Council and we will shape the presentation and the frequency of offering it, based upon the Council's preferences."

Further discussion ensued regarding Dr. Gillick's amendment to require disclosure of free samples and not exempt it from the disclosure requirements of the regulations. Mr. Albert Sherman seconded Dr. Gillick's amendment so discussion could continue. During discussion Chair Auerbach clarified, "The primary reason for this particular exemption from disclosure of sample medications came from the organizations that Ms. Caulton-Harris was referring to, which was primarily a lot of homeless shelters, and a lot of organizations like Health Care for the Homeless, where the concern was that, if the donation of free medications became onerous for pharmaceutical companies, that they be less inclined to be able to make what in some instances are considerable donations of free medications to those organizations." He further pointed out that

some indigent patients are uninsured and/or have conditions in their lives that make prescription filling difficult for them.

Mr. Lanzikos stated in part, "...I plan not to vote in support of this [Dr. Gillick's amendment] for this reason. I would like to get more information. I don't know what the scope of the reporting is, what is the volume of the reports, what the value is. I would suggest that staff sort of monitor this and come back with recommendations in the future that they see as warranted...We are pushing the edge of the envelope already considerably, and I think commendably so. I am just concerned that we could overwhelm a very important new public process with a level of reporting that sort of gets in the way of the real essence of what we want to get at. I would urge us maybe to move a little slowly on this, pay attention to this, and come back in the future if we have to amend the regulations, if we feel that this is creating a loophole."

Attorney Lopes noted that the statute requires staff to revisit the regulations every two years and make changes as needed so that anything staff notices in the first two years can be revisited. Dr. Meredith Rosenthal added, "Perhaps one specific way of thinking about this would be to bring some these comments together and say that we would like to look at sampling over time as a potential unintended effect on this regulation. You can imagine, if we shine the light on certain areas of influence, others, those that are not in the light, may grow, and there are available data by which one could, and the Department or outside researchers could look at the use of free samples in Massachusetts. The prescriber identified data, for example, would allow us to look at use by physician and data can be obtained through the industry that look at sampling and detailing of specific physicians. I think that is something that we might want to consider as something to examine as we go forward." Chair Auerbach and Dr. Dreyer indicated that this could be included in the list of activities for consultants to assist on in terms of the implementation of the regulations.

Ms. Caulton-Harris said in part, "...I live in a city where the poverty rate is very high, forty percent, and it means that samples and health

care become critical to those individuals who are looking to maintain some level of quality of life in terms of their health care. While, I think it is important to monitor this, I also think it is important to not have this in the original regulations so that people can continue to get the samples that often are life saving, as far as their health is concerned."

Earlier in the discussion, Dr. Cunningham suggested that maybe there could be a cut-off threshold where after so many medications are prescribed to an individual, it would then be reportable. At this point he said, "...I think we are trying to do the same thing. It is just how to go about it....I am now taking my threshold idea off the table and saying, is there a way to separate the kinds of groups that can be exempted from receiving versus reporting for others?"

Dr. Rosenthal added further, "...There are such things as 340B organizations that are exempted from the Medicaid pricing legislation that surrounds the rebate process. There is a classification of essentially organizations that get low cost or free pharmaceuticals for the distribution to low income populations as we talked about already. So that might be a logical group to look at, these 340B organizations..."

Attorney Lopes said in part,..."We are exempting from the definition of disclosure of all sales and marketing activities, rather than the person that the benefit is going to so any exemption we do might inadvertently go to all of the covered recipients..."

Dean Harold Cox inquired whether the Council could table Dr. Gillick's amendment only and still go forward with the overall regulations. Chair Auerbach noted that it would not be that simple; to approve the regulation with an amendment would require another formal hearing process to revisit the amendment. Therefore, Dr. Gillick retracted her motion and Mr. Sherman withdrew his second of the motion.

Discussion continued and it was decided that collecting information on free samples would be a sub regulatory procedure (no vote

required). Chair Auerbach noted for the record, "It is the will of the Council that we agree that the Department will make an effort to gather more information about sampling practices, both in terms of who benefits from them, who receives them, and if there are ways of making distinctions between the use of samples for vulnerable populations versus for other purposes, and come back to us within a set amount of time, and the Council can consider at that point an amendment to the regulation."

Mr. Lanzikos made a motion "asking that a phrase be inserted on page six of the regulations, section (g) last sentence, that states, 'must give health care practitioners the opportunity to affirm that their prescribing data may be made available to company sales representatives and that it may be used for marketing purposes,' or language to that effect and as I said earlier that would be consistent with the way we now require prescribers to affirm the use of brand name pharmaceuticals."

Discussion continued about data being collected at the pharmacy transaction level on individual physicians and also aggregated data. DEA numbers are linked to AMA data on individual physicians. Pharmaceutical companies use the prescriber identifier data. Drs. Rosenthal and Avorn concurred on this. Mr. Lanzikos withdrew his motion above regarding inserting the phrase that health care practitioners must agree to have company sales representatives use the data for marketing purposes on the condition that more research be done on this as with the sampling question and staff bring the information back to the Council. Dr. Dreyer noted that the two requested research requests should be contingent on his bureau receiving the retained revenue funding. Chair Auerbach agreed that without resources they couldn't do it. Ms. Prates Ramos asked that the Council revisit the regulations in one year or less instead of two years.

Chair Auerbach summarized the agreed points of discussion: "We are agreeing to, as a Department, in terms of the administrative implementation of the regulation, that within a period of time, not more than one year, we will come back to the Council for the

reconsideration of the content of this regulation. We will look at what we have learned during that period of time in attempting to implement it, with a particular focus on the two areas that have been mentioned; one was the sampling issue and the other is with regard to utilizing practitioner prescribing data reports, whether or not we want to put in place additional restrictions on that, or additional rules that govern access to that information.”

Attorney Lopes added for the record that the compliance with the regulations begins on July 1, 2009 with the first disclosure reports due by these companies on July 1, 2010, covering the period from July 1, 2009 until December 31, 2009. She inquired, “Isn’t that when we should revisit these regulations?” Chair Auerbach responded, “...It’s helpful to have that in mind. I think we still will have additional information about the implementation process itself, the designing of the forms, the initial interaction with the groups involved and we can commit to do the independent research and that independent research may involve surveys and/or focus groups. There may be certain activities we can do in less than a year which will not be impeded by the data just coming in on July 1...”

Dr. John Cunningham moved approval of the regulations. After consideration, upon motion made and duly seconded, it was voted: (Mr. Lanzikos, Ms. Prates Ramos, Mr. Rivera, Mr. Auerbach, Mr. Sherman, Ms. Caulton-Harris, Dr. Rosenthal, Dr. Cunningham, Dr. Gillick and Dean Cox in favor; Drs. David and Wong recused; Mr. Leary and Drs. Woodward and Zuckerman absent) to approve **Final Promulgation of Regulations 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct** and that a copy of the approved regulations be attached and made a part of this record as **Exhibit No. 14, 923**.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETING OF DECEMBER 10, 2008:

Mr. Sherman made the motion to approve the December minutes. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Minutes of the December 10, 2008

meeting of the Council as presented. A copy of the minutes had been distributed to the Council prior to the meeting for their review.

ANNOUNCEMENT:

Chair Auerbach noted that Council Member Helen Caulton-Harris will be receiving the highest award on May 15, 2009 from the Massachusetts Public Health Association for recognizing her outstanding public health leadership.

PRESENTATION: "ACADEMIC DETAILING: EDUCATING PHYSICIANS ABOUT PRESCRIPTION DRUGS", BY DR. JERRY AVORN, INTERNIST, PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, CHIEF OF THE DIVISION OF PHARMACO EPIDEMIOLOGY AND PHARMACO ECONOMICS AT THE BRIGHAM & WOMEN'S HOSPITAL, AND UNPAID CONSULTANT TO THE INDEPENDENT DRUG INFORMATION SERVICE

During his presentation Dr. Avorn noted that medical schools don't teach doctors enough about evaluating sources of information about prescribing. He said in part, "Continuing medical education is a real problem area in that a high proportion of it is indeed funded by the pharmaceutical industry...The last point is the most important. It is no one's job out there to make sure that doctors have access to evidence-based, unbiased, non-commercial information about what we prescribe, and certainly the companies have their job and they do it very effectively, but there is not a public sector job that is comparable, and the other issue is the FDA will declare a drug acceptable for marketing if it has shown itself to be sometimes just better than nothing...and is dependent on the industry's own studies...We doctors don't know what drugs costs, or what kind of coverage our patients have or don't have and there is an enormous amount of marketing...The FDA budget is two and a half billion dollars compared to the American Drug companies spending five billion dollars a year on consumer marketing...We really need evidence-based non-product driven effective communication to prescribers about drugs and I would submit that is a public good, just like having clean air or highways, or water that is drinkable. This is

something which a government should make available to its citizenry."

Dr. Avorn said further, "...The question I raised in a grant application in the 1970s, would it be possible to take the content of evidence-based medicine and use the delivery system of drug companies, of getting somebody into the doctor's office who is articulate and brief, and user friendly, to provide evidence-based information and not just to sell their company's product...The goal is to close the gap between the very best available science and actual prescribing practice so that every prescription that gets written is based on the most current accurate evidence about efficacy, safety, and cost effectiveness and to get that information out to doctors in a way that will really change their practice in an efficient manner, so that ideally every patient in Massachusetts, seen by every doctor in Massachusetts, would be, in the extreme, getting the most appropriate therapy on any day of the year."

Dr. Avorn noted that he has been working on this for 25 years first in research mode and now in service mode. They [he and his colleagues at Harvard Medical School] conduct comprehensive reviews of the medical literature...and then produce readable evidence documents that the academic detailers distribute to doctors. The information can be accessed on the web at RXFACTS.org. Materials are created for patients too so they understand, for example why they don't need antibiotics for a cold.

In closing he said, "So to wrap up, where we stand, with enormous help from Andy Epstein and Cheryl Bartlett, and the leadership of the Department of Public Health, we have now got two ace academic detailers hired, and up and running in Massachusetts. One is a physician and one is a nurse, and we are working with the League of Community Centers to identify their medical directors and associate medical directors as a congenial home to start this, and I am pleased to announce that, as of last night, we have made contact with Mass Health and Paul Jeffreys has gotten back to us and said that he would like to help provide us information on doctors who are heavy prescribers in Mass Health, and the virtue of having those data is that

...we will be able to look at the prescribing by those docs compared to the prescribing by other docs who are not offered the program, and see if we are really making a dent... We are delighted to have the opportunity to do this pilot and we are very excited about getting it off the ground."

Discussion followed by the Council (see verbatim transcript for Dr. Avorn's full presentation and Council discussion). Dr. Gillick asked Dr. Avorn if he has experimented with webinars and interactive computer stuff to get his information out. Dr. Avorn replied in part, "...I suspect the ultimate best solution to this will be some combination of interactive technology for those doctors that are on the computer for their prescribing, offering perhaps CME credits for somebody to log onto a webinar but there are so many lectures around offering CMEs already but if we could motivate for them to use the electronic medical record or perhaps requiring doctors to log on to a web site and spend at least ten minutes reviewing materials as a step in license renewal that wouldn't be a bad idea...A combination of high tech and high touch is probably the best thing for now."

Dr. Michael Wong, stated in part, "...I think this is wonderful. As an academic physician who also works in a community health center and goes around the country trying to do a lot of very evidence-based education and training to other physicians who are providers on HIV medications and antimicrobials, I can't say enough about this kind of effort. It absolutely needs to be done..." Dr. Wong also noted that the problem with on-line information is some sites look legitimate but turn out to be underwritten by pharmaceutical companies but the sites fail to mention the source of the information. Dr. Michéle David noted that the problem is physicians are only given the wholesale prices of medications and not the retail prices and when her patients go to the pharmacies they are charged ten times the wholesale price. In response, Dr. Avorn added they include prices in his information for doctors; however, the price the patient pays for the medication also depends on what pharmacy they go to fill the prescription. Dr. David said a systemic approach is needed. Dr. Avorn noted that in Pennsylvania, they are launching a web site that does what Dr. David

is suggesting, it displays in every area, you can search by zip code, price information for every drug that every pharmacy sells and they make pharmacies provide that information. They get it from their own reimbursement data. They are finding enormous differences in prices even within the same neighborhood. I think that might be a useful service we could think about here."

Council Member Josè Rafael Rivera stated, "An educated consumer is just as important as an educated provider...I know that people in my culture have a very difficult time challenging or even questioning a physician. How do you educate people to have these conversations?" Mr. Rivera said it would be helpful for Dr. Avorn to build capacity with the Community Health Workers who have access to a lot of cultural and linguistic different groups. Dr. Avorn noted that they give doctors materials for patients and the other source for consumer information is a web site provided by Community Catalyst at GenericsArePowerful.org that provides information on what the drug ought to cost, how to ask for generics and how to talk to your doctor and what questions to ask etc. Dr. Avorn agreed that contacting the community health workers is a great idea and that he would love to get the generic materials and the Community Catalyst information to various groups around the state.

Mr. Paul Lanzikos suggested that Dr. Avorn that maybe he could do an in-service with the Executive Office of Elder Affairs program people called SHINE, which is trained volunteers that primarily educate consumers around their choices for health insurance products, including Medicare Part D, which would be another way of disseminating the information. Mr. Lanzikos said he would like to see the Pennsylvania web program here in Massachusetts. It was noted that academic detailing is being discussed on the Federal level.

Chair Auerbach thanked Dr. Avorn and suggested that maybe he come back to the Council meeting some time and discuss ways to insure more people have the information, both clinicians and non-clinicians because it makes so much sense.

NO VOTE/INFORMATION ONLY

FOLLOW-UP ACTION STEPS:

- Regarding Regulations 105 CMR 970.000, add additional research fields to the web page (Lanzikos, Dreyer, Auerbach)
- Regarding Regulations 105 CMR 970.000, solicit input from focus groups on what content should be on web site (Lanzikos to Lopes, Dreyer)
- Have Trade Groups who presented testimony on 105 CMR 970.000 distribute a communication to their membership informing them of these regulations (Lanzikos to Lopes)
- Regarding Regulations 105 CMR 970.000, Review the data collected for intended and unintended effects (Cox to Auerbach, Dreyer)
- Regarding Regulations 105 CMR 970.000, collect information on free sample medication practices in terms of who benefits from them and who receives them and if there are ways of making distinctions between the use of samples for vulnerable populations versus for other purposes and bring the information back to the Council (be included on list of activities for the consultants to assist with) (Council to Dreyer) [research contingent on funding]
- Regarding Regulations 105 CMR 970.000, research be done on health care practitioners prescribing data availability to company sales representatives for marketing purposes (Council to Dreyer) [research contingent on funding]
- Bring Regulations 105 CMR 970.000 back to the Council for further consideration in not more than one year, with focus on the sampling issue and practitioner prescribing data reports (Auerbach to Lopes)

- Regarding Academic Retailing Program - suggested to Dr. Avorn that he build capacity with the Community Health Workers who have access to a lot of cultural and linguistic different groups (Rivera to Avorn)
- Regarding Academic Retailing Program – suggested that Dr. Avorn maybe do an in-service with the Executive Office of Elder Affairs program SHINE as another way to disseminate the information (Lanzikos to Dr. Avorn)
- Maybe have Dr. Avorn come back to the Council again to discuss ways to insure more people have the information, both clinicians and non-clinicians (Auerbach to Avorn)

The meeting adjourned at 12:15 p.m.

John Auerbach, Chair

LMH