



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
 Governor

MARYLOU SUDDERS
 Secretary

KARYN E. POLITO
 Lieutenant Governor

MONICA BHAREL, MD, MPH
 Commissioner

Tel: 617-624-6000
www.mass.gov/dph

**Massachusetts Department of Public Health
 Minutes of the Drug Formulary Commission
 Meeting of Monday, February 5, 2018**
 Henry I. Bowditch Public Health Council Room, 2nd Floor
 250 Washington Street
 Boston, MA 02114

Date of Meeting: Monday, February 5, 2018
Beginning Time: 9:05 AM
Ending Time: 11:42 AM

Advisory Council Members Present: The following (12) appointed members of the Drug Formulary Commission attended on February 5, 2018, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Professions Licensure Director James Lavery (Chair); Dr. Douglas Brandoff; Cheryl Campbell; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Stephen Feldman, Dr. Kenneth Freedman, Dr. Paul Jeffrey, Logan Leslie; Tracey McMillan; Cindy Steinberg; Dr. Jeffrey Supko.

1. Welcome and Introductions

James Lavery called the meeting to order at 9:05AM.

Mr. Lavery thanked everyone for being here today, and reminded everyone that the meeting was being recorded. He then asked if anyone was recording, receiving no affirmative response.

Mr. Lavery provided a brief recap of the last meeting on December 14, 2017, where commission staff presented the timeline for promulgation of the proposed revision of 105 CMR 720, *The Drug Formulary Commission*, which includes the first draft formulary; discussed the development of prescriber education; and sought the commission’s input on speakers to hear from on the issue of cost impact.

Mr. Lavery reminded the members that all currently approved drugs were included on the first draft formulary in the regulation, and no new drugs have been presented for approval in Component 2 for the second draft formulary yet.

Mr. Lavery stated the goal for today’s meeting: to hear from some experts on cost impact considerations of abuse deterrent substitution

Mr. Lavery called for approval of the minutes from the December 14, 2017 meeting.

Motion to Approve: Ms. Steinberg

Second: Dr. Doyle-Petrongolo

All in favor: 10; Opposed: 0; Abstentions: Ms. Campbell, Mr. Feldman

2. Cost Impact Review

Mr. Lavery reminded members that, at our last meeting, we discussed our plan to invite experts to speak to you about “cost impact”, one of the four criteria for determining whether a drug is a chemically equivalent substitution. Ultimately, we are looking to answer your question “what does it mean for an abuse deterrent substitute to be cost prohibitive?”

Mr. Lavery informed members that we would hear from several speakers today, and asked the members to introduce themselves.

Members introduced themselves to the speakers and the audience.

Mr. Lavery noted that, Pursuant to Chapter 258 of the Acts of 2014, the Commission is tasked with getting expert feedback to consider as part of its work to develop the formulary, and reminded the members that the commission did this once before, on October 1, 2015, when the commission was just getting started, to introduce members and staff to the concepts of drug efficacy, ADP efficacy, accessibility, and cost effectiveness.

Mr. Lavery then introduced the first speaker:

- Joshua Cohen is a health economist with 25 years of experience analyzing trends in prescription drug pricing and reimbursement, patient access to biopharmaceuticals, and use of clinical and cost-effectiveness in clinical practice guidelines. Joshua came to us through the Tufts University Center for the Study of Drug Development, and is currently a consultant.
- Today, he will speak on a number of topics including uneven payer coverage, the difficulties with budget impact analyses, and the concept of patient stratification.

Joshua Cohen presented on “Patient Access Challenges Facing Abuse-Deterrent Formulations of Opioids Analgesics”. See Attached Cohen Slides

Dr. Cohen noted that Medicare coverage of ADFs is less than 50%.

Ms. Steinberg asked if his figures on slide 10 separate immediate release against extended release in comparison to ADF and non-ADF.

Dr. Cohen answered that he is not sure.

Dr. Carr stated that it does not make sense for methadone ER to be listed on the ER section in slide 12 since regular methadone is long acting and/or has a long half life.

Mr. Leslie asked how good of a sense does Dr. Cohen have for these numbers and the different risks that are associated, such as buying and using versus buying and selling.

Dr. Cohen explained that these numbers are not good for the amount of diversion. He goes on to state that there are inconsistencies between studies and that he does not know the percentage of patients getting non-opioid therapies. He noted that physicians are rushed through assessments and prescribing opioids.

Dr. Cohen asked ICER if they used any risk stratification in the VA studies.

ICER answered no.

Dr. Carr asked about key policy challenges. Where would you spend your money?

Dr. Cohen responded that he would recommend a thorough analysis on which patients should be switched to ADFs and which ones should not.

Mr. Leslie asked if there is any cursory analysis of cost impact when scale is achieved.

Dr.Cohen stated there is no cursory.

Dr. Carr suggested that a potential side topic to guide the mission when you describe the key policy would be to prioritize certain key policies or measures.

He asked Dr. Cohen if he has any suggestions of which policy is most important.

Dr.Cohen explained that ICER analysis and REMS program is most important. Also that cost-effectiveness is most important. Second it may not be appropriate to switch all patients to ADF. Also, needs to be a way to determine who would be switched from non-ADF to ADF. He ends with stating this will have a direct impact on the budget.

Ms. Campbell asked what percentage of the advocacy will affect the pre and post-market assessment.

Dr.Cohen explained that the post market assessment for ADFs is not well established. But from 1000 other drugs pre and post market data we can assume that drugs which had large clinical trials are more consistent than small number clinical trials like orphan drugs. These drugs could have big positive or negative surprises. There is no rule to determine to get a specific number but he is assuming that the pre and post market will be consistent. There are only pre-market. We cannot say this is the rule, we need categories.

Ms.Campbell asked about the risk.

Dr.Cohen explained that we need to extrapolate but can be surprised. Most countries only base their information on pre-market studies.

Mr. Lavery reminded members that it requested a benefit review last year, as authorized by chapter 258 of the acts of 2014. As introduction, Mr. Lavery informed them that the next speakers are from the Center for Health Information and Analysis (CHIA), which conducted that review and intends to expound on that review today.

- CHIA has three speakers today. You will likely recognize Ray Campbell, the Executive Director, and a former member of the DFC. He is accompanied at the table by Margaret Anschutz, Special Projects Manager at CHIA.
- Joining them by phone are staff members at BerryDunn accounting and consulting firm, including:
 - Valerie Hamilton, policy analyst;
 - Amy Raslevich, healthcare consultant; and
 - Dr. James P. Highland, a health economist and financial consultant.
- Their testimony will include a background of CHIA and its data assets, as well as its role in conducting Mandated Benefit Reviews. The panelists will then provide a brief overview of the scope and findings of the December, 2016 Actuarial Analysis for the Drug Formulary Commission.

CHIA presented the results of its December, 2016 Actuarial Analysis for the Drug Formulary Commission. See Attached Review

Ms. Steinberg asked if the legislature is the only entity to ask questions to CHIA or if anyone else can.

CHIA explained that anyone can make the request. They have answered many questions from DPH.

Ms. Steinberg then asked if this review falls under the chapter 55 Study or DPH.

CHIA stated that it would fall more under DPH because CHIA is simply data integration.

Dr. Carr asked why estimates provided to the commission during ADF evaluations showed costs but this review showed potential savings?

Mr. Thompson stated that the DFC ADF evaluations looked at 2015-2016 wholesale acquisition cost for the drug cost. They attempted to get the real cost of the drug and determined this number by finding the cost per milligrams and got a range from 50 to 100 percent, which provided blunt estimates.

CHIA stated they had limited data and had to make assumptions.

Ms. Nelson stated that DFC ADF evaluations were studied per individual drug, so there were both small and large differentials.

Dr. Thompson agreed that there was some overlap in substitution.

The speakers on the phone stated that the study was very limited so they had to make assumptions. They would make the assumptions regardless of law.

Ms. Steinberg asked about subtraction from the review?

The speakers on the phone explained that it would be difficult to pull the number during the meeting but they used DFC figures and the PMP.

Ms. Steinberg asked about the uptake, assuming 60% uptake. She also stated that 4.1 million is 70%. Could you tell us what you subtracted off?

The speakers on the phone explained that the 4.1 million is the midpoint uptake or 70 % and a low would be 60 % and a high of 90%. They explained that they could go back in the data and subtract the uptake.

Ms. Steinberg asked about at what point in our formulary was the report analyzed?

The speakers on the phone explained that the formulary was from November 2016 but Embeda was on it.

Ms. Steinberg stated that since it was somewhat based off the formulary, the formulary was not finalized when they were getting the data.

Ms. Nelson stated that only 4-6 ADFs were done at the time.

Dr. Carr stated that the study is nicely done but notes that non-ADF and ADF may come in different doses and there may be other ways that we can not compare. We need to be willing to define the data on different methods and assumptions.

Dr. Thompson stated that if non-ADF comes in strengths that ADF does not, then there cannot be a substitution by definition of chemically equivalent.

Ms. Steinberg asked if we can get the dosing from PMP or some other source like the manufacturer. She stated that there has to be a database that is tracking these sales.

Mr. Thompson explained that we do have the data on PMP but it is not feasible and would only be possible with extended time.

Ms. Nelson stated that they can certainly look into it.

The speakers on the phone stated that the timelines were much different than the one Dr. Thompson was looking at.

Mr. Lavery asked if they said their PMP was from 2015.

The speakers on the phone said yes, but they could not get all the information since there is a 6 month lag.

Ms. Steinberg stated that now that the formulary is complete they can update their information.

Dr. Carr stated that he is still not sure which would be the best assumptions.

CHIA stated that it is always best to be specific.

Mr. Lavery calls the discussion to a close and explains there are many things to consider here.

Mr. Lavery stated that there were several requests for our next panel of speakers based on their August 8, 2017 final evidence report: *Abuse-Deterrent Formulations of Opioids: Effectiveness and Value*. He then introduced the Institute for Clinical and Economic Review, represented today by:

- Sarah Emond, Executive Vice President and Chief Operating Officer. She leads the strategic planning and operations of ICER and is responsible for overseeing ICER's public programs, communications, operations, and finances.

- Dr. Foluso Agboola, Research Scientist. She joined ICER in 2016 and is responsible for conducting systematic reviews and comparative effectiveness research.
- Varun Kumar, Health Economist. He oversees and develops economic evaluations that assess cost-effectiveness, budget impact, and monetary value of a wide range of health technologies, treatments, and interventions in the United States health care landscape

Mr. Lavery announced that ICER would discuss their report findings and recommendations, including:

- Extended-release ADF opioids have the potential to reduce abuse in opioid-prescribed chronic pain patients, but at substantially higher costs to the health system and society, and
- Policymakers and clinical leaders should consider measures to phase in ADFs while ensuring adequate support for other elements of a multi-pronged approach to the opioid crisis.

The Institute for Clinical and Economic Review presented on “Abuse-Deterrent Formulations of Opioids: Effectiveness and Value”. See Attached ICER Slides and Report.

Dr. Freedman asked how they got the numbers for abuse rates that were used to formulate economic model.

ICER stated they were from the economic model and can be fully seen in the report.

Dr. Carr stated that they should consider a hypothetical experiment, with the new legislation in place, and look at limiting the supply after surgery and focus on the people who would require more, who might be given an abuse deterrent formulation. Suggests potentially setting up a threshold on the doses and the 20-80 rule.

ICER stated they wanted to target high risk, high value patients, high dose duration but it is opinion based and there was no evidence on how to identify these patients. ICER went on to state that most clinicians do not like the stratification tool and this makes it difficult to identify these patients. One suggestion would be to not look at 3-day ER and 7-day first time prescriptions.

Mr. Leslie asked how easy it would be to tweak the model so the commission can use it with other variables.

ICER states they could change the assumptions by adding in different inputs. They are willing to work with DFC if we have new data ideas.

Mr. Leslie stated he would like to look at the Massachusetts model and how many lives saved.

ICER explained that it is difficult to predict for Massachusetts because it can be too sensitive and having one decimal change will change the results greatly.

Ms. Campbell asked which patients they based their analysis on, only those that were prescribed an opioid.

ICER stated that it was only based on patients who were prescribed opioids.

Ms. Steinberg stated that abuse is much smaller than we realize. Of the medication prescribed only between .12% and 8% of patients end up abusing the medication. She stated that the more important issue is illicit drug use and we should be focusing on that issue. She states the media makes abuse by legitimate pain patients look much worse than it is.

Mr. Lavery stated that this is why it’s so important to look more at risk stratification.

Ms. Steinberg stated that prescribing of these medications is down and deaths are up from illicit substances. She stated that illicit substances are the number one cause.

ICER stated that it is hard to find information on diversion.

Ms. Steinberg stated that this data is available.

ICER stated that most information on diversion comes from police reports which are not reliable. And there is not data available on how many patients then switch to heroin.

Ms. Steinberg stated that the data was reliable, the CDC publishes this information.

Ms. Nelson asked what ICER's definition of diversion is.

ICER stated that it is prescription medication getting to a different person than prescribed for.

Ms. Steinberg asked about the cost impact of people taking this medication who actually need it and not in the risk stratification tool.

ICER stated that is it tough to model since it varies payer to payer. It is all unique and can continue to do more methodology to get results.

Ms. Nelson noted that Chapter 258 prohibits increased cost sharing.

Dr. Jeffrey stated that insurance companies can pass that cost on another way

ICER stated that they do this with premiums

Dr. Carr stated there are limited instruments for the safe and effective use of opioids. But if the commissioner requested it then we can do it quickly.

ICER stated that their take home message is that they have limited data and there is not a single prospective marketing study, despite requirement that manufacturers conduct them.

Ms. Campbell asked if anyone has looked at the market size.

ICER stated that prospective studies are feasible and they would not need to change all data points.

Mr. Lavery stated that next meeting they should come up with one to two data points they can change

Ms. Nelson stated that they can see where cost shift balance changes are with graduated data.

ICER stated that it can be difficult because some manufacturers are private and it is hard to get that information so they look at earning reports of the non-private companies.

Dr. Jeffrey stated that ICER's analysis determined a price reduction of 41% by ADF manufacturers was necessary to make the Massachusetts drug formulary substitution policy cost neutral.

Mr. Leslie asked if this population was taken from the VA.

ICER answered that no, that was a separate analysis

Mr. Lavery thanked all of the panelists for attending today's meeting and for their thoughtful remarks and engaging discussion.

Mr. Lavery stated that he hoped this information would help members in thinking more about the work that remains as we put together the second draft Formulary. He noted at our next meeting, there will be an opportunity to discuss thoughts and feedback to develop comprehensive criteria for determining whether an IAD is cost prohibitive such that it should not be included as a therapeutically equivalent substitute.

Mr. Lavery told members Ms. Nelson would notify them once all of the written testimony is available online.

3. Draft Formulary and Regulation

Mr. Lavery reminded members that the public review and promulgation process for 105 CMR 720, which was approved by the Public Health Council on August 9, 2017.

Mr. Lavery stated the regulation will take effect once it is filed with the Secretary of State, which will occur at least 30 days after the prescribing and dispensing guidance is distributed to begin the education and outreach process.

Mr. Lavery stated he will keep everyone informed if there is any movement on this process

Mr. Lavery asked if there was any further discussion.

Dr. Carr asked how to wrap up loose ends given that the cost implication is incomplete with a 100-fold variation in estimates based on information provided.

Mr. Lavery answered and stated they will fix it next meeting and as a committee we can decide without all the information or whether we need more time before making an informed decision.

4. Drugs Products for Future Consideration

Mr. Lavery reminded members that at the last meeting, we discussed our plan to present a new drug for your evaluation, however we decided the presentations and the evaluation in one meeting would be a tight squeeze, so we expect to present RoxyBond at the next meeting.

Dr. Thompson informed members that this was his last meeting and thanked everyone for his time here.

Mr. Lavery introduced Karen Stevens as the new pharmacist consultant from UMass.

Mr. Lavery stated that as the FDA continues to review and approve drugs with ADP properties, and more of these drug products are brought to the US market, the Commission will need to determine how these drugs may interact on the Formulary.

Mr. Lavery also stated that if information comes to light at any time to potentially change the evaluation of an existing drug product on the formulary, the product can be added to the agenda for reconsideration.

Mr. Lavery asked if there were any questions or comments on these drug products or this process.

5. Meeting Schedule

Mr. Lavery thanked the Commission members for their thoughtful comments and questions and the speakers for providing important information. He will update the committee with any updates related to the effective date of the regulation and the distribution of the guidance.

Mr. Lavery anticipates monthly meetings to continue to be held on the 3rd Thursday of each month, from 9:00-12:00PM in this room, with a few exceptions

Mr. Lavery stated that because this meeting was rescheduled to the beginning of this month, we will not meet on February 15th as originally scheduled.

Mr. Lavery also notified members that the April 19th meeting would be cancelled due to School Vacation Week and other staffing consideration.

Mr. Lavery noted that it will be necessary to meet in August to update the Non-Opioid Pain Management List, which must be approved and posted online by September 1, 2018.

Mr. Lavery notified members the next meeting is anticipated for March 15th at 9:00AM.

6. Closing Remarks/Adjournments

Mr. Lavery asked for any final discussion or questions, and hearing none, called for a motion to adjourn.

· Motion to Adjourn: Ms. Steinberg

· Second: Mr. Feldman

· All in favor: Unanimous

Meeting adjourned at 11:42AM