

NPA Avoiding Conflict-of-Interest in Medicine Leadership Development Call Series Archive

**Massachusetts Gift Ban Rules:
Rallying to Limit Industry Wining and Dining
December 19, 2012 CALL NOTES**

Facilitator: Rachel DeGolia, Board Member of the National Physicians Alliance and Executive Director of the Universal Health Care Action Network (UHCAN)

1. Welcome and introductions

Rachel: This Conflict-free Leadership call is hosted by the National Physician's Alliance as part of its Unbranded Doctor project, which takes place under the Partnership to Advance Conflict-free Medical Education (PACME) grant. The PACME grant is the result of a state Attorney General settlement regarding the marketing of the drug Neurontin. Partners for the grant include the National Physicians Alliance, American Medical Student Association, Community Catalyst and the Pew Charitable Trust, and staff for all these organizations are on this call.

The goal of the project is to reduce conflicts of interest created by the pharmaceutical industry in the medical profession and medical research. The partners on this grant promote a number approaches to raise awareness of the issue and to build leadership in the medical profession to eventually eliminate some conflicts. For more information about the National Physicians Alliance and PACME, visit the NPA Unbranded Doctor Website at: www.npalliance.org/conflict-free

Our speakers tonight will be:

- **Alyssa R. Vangeli, JD, MPH** - Health Insurance and Delivery System Policy Analyst for Health Care for All (HCFA) in Massachusetts <Alyssa@hcfama.org>
- **Mary Carol Jennings, MD** – a member of the Board of Directors of NPA and past Jack Rutledge Legislative Director for the American Medical Student Association (AMSA) <marycaroljennings@gmail.com>
- **David Tian** – National Chair, AMSA PharmFree; MD/MPP Candidate, Harvard Medical and Kennedy Schools (Graduating May '13), <dctian@gmail.com>

Speakers will describe the **Massachusetts Prescription Reform Coalition** (MPRC) efforts to strengthen proposed regulations allowing “modest meals and refreshments” to be served during educational presentations sponsored by pharmaceutical and medical device companies. The Massachusetts 2008 gift ban law prohibited these companies from providing gifts, such as restaurant meals or entertainment, to doctors, nurses, and other health care providers, as part of industry marketing practices. The law was recently amended to allow drug and device companies to provide food and drinks at educational presentations outside of the hospital or office setting. Speakers will describe the MA gift ban law, efforts by the industry to weaken it and the status of the final rules allowing for the

provision of meals and refreshments. They will also discuss their on-the-ground advocacy role as coalition members in working to strengthen the regulations to preserve the intent of the original law.

2. Partnership for the Advancement of Conflict-free Medical Education (PACME) brief overview:

Ann Woloson, Director of Education for NPA -- This is the sixth of a series of calls which take place on a bi-monthly basis offered by the NPA. The calls are all archived on the NPA website, www.npalliance.org/conflict-free, along with a series of national Grand Rounds which are taped and webcast and which provide continuing medical education credits. The topics are very interesting and all related to conflict-of-interest issues. Our most recent National Grand Rounds included an overview of strategies by the pharmaceutical industry to market products to physicians and consumers using techniques including technology, drug reps and coupons.

Our speakers on this call provide a great example of how physicians and medical students can work together to shape policy

3. Alyssa R. Vangeli, JD, MPH - Health Care For All (HCFA), Health Insurance and Delivery System Policy Analyst

Alyssa: Health Care for All (HCFA) is a nonprofit focused on health policy and advocacy in Massachusetts. At HCFA, I lead the Massachusetts Prescription Reform Coalition (MPRC), which includes community, local and national organizations and providers committed to evidence-based, unbiased prescribing and access to appropriate and affordable prescription drugs. Our most active members are AARP of MA, MassPIRG, Community Catalyst, NPA, and AMSA. Our focus the past few years has been upholding and defending the Gift Ban Law and promoting funding for academic detailing.

The full title of the Gift Ban Law is the Pharmaceutical and Medical Device Gift Ban and Disclosure Law and it was enacted as part of a larger bill to promote cost containment, transparency and quality of care. Implementation began in 2009. The purpose of the law is to curb the influence that pharmaceutical and medical device industry gifts have on health care provider prescribing patterns and industry interactions with administrators and providers. Much of the law it is still intact today, but the original law prohibited drug and medical device companies from providing any gifts of restaurant meals, entertainment, tickets and other smaller gifts to doctors, nurses and all other prescribers in the state as part of their marketing practices. The law does require the reporting of any allowable provider payments from the industries to the Department of Public Health which is posted on their website. The law does not limit compensation for research, restrict clinical trials, or prohibit meals within the provider setting that are part of information presentations by the companies.

The Gift Ban Law has been under attack since it was passed. Attacks in the Initially, the targeted industries were behind these efforts, but more recently the restaurant industry has led the attacks claiming that the prohibition on industry representatives taking prescribers out for meals has hurt their industry. We think the restaurant industry was pulled into this by the pharmaceutical and medical device companies, which was a smart move for them. Since passage of the law, the House has led efforts to weaken or repeal the law, and the Senate has upheld it. Our Governor has not been a big supporter of the law. MA is a big hub for both industries and the Administration is concerned that they are being hurt by it, despite lack of any evidence that this has been the case.

Last year, the House budget contained a full repeal of the law. The Senate budget had nothing on it, but in reconciliation they reached a “compromise” that weakened the law. The companies are now allowed to provide “modest” meal and refreshments in connection with non-CME presentation

outside of the prescriber setting in a manner “conducive to informational communication.” Also, there were changes to increase the disclosure and reporting requirements regarding the companies to file quarterly reports as to the location, description of the products discussed and amount spent as well as participants at the meals. Some of these strengthening measures will be preempted by the Physician’s Payment Sunshine Act, however.

From January through June, the Coalition worked hard, holding one-on-one meetings with legislators, testifying at hearings, bringing in experts to meet with legislators, releasing press statements, organizing consumers to call their legislators, and reaching out to providers who wrote op/eds. While the law was not entirely repealed, as we had feared, it was significantly weakened.

The MA Department of Public Health was charged with defining “modest meals” under the law. The Coalition weighed in, advocating for a dollar cap so that it would be measurable and enforceable, and also pushed for using federal reimbursement rates as the standard, which allows dinners up to \$35. We urged that alcoholic beverages be banned during these informational presentations and pushed for the strongest possible reporting requirements. After a period of time during which there was no definition of “modest meals,” the Department issued “emergency regulations” defined them as “food and drink as judged by local standards would be what a health practitioner might purchase at their own expense.” During the 30-day comment period we organized public comment, but did not prevail. Thus, the companies have free rein to spend what they wish and provide alcohol at these events as well. However, the Public Health Council, which approved these regulations, gave the Commissioner of Public Health discretion to require additional information from companies, so this may lead to collecting data that can be used to establish stronger regulations in the future.

Q: Are there physician groups that opposed the weakening of the law, including the Massachusetts Medical Association (MMA)?

A: The MMA supported the original law but subsequently changed their position to support weakening it.

Q: Were players that were involved in passing the original law in 2008 involved in defending it?

A: Most of the groups involved at the beginning were at the table defending it, including consumer groups. It was a broad coalition that stayed involved and were disappointed when it was weakened.

4. David Tian, National Chair, AMSA PharmFree Project, a student at Harvard Medical and Kennedy Schools, and, **Mary Carol Jennings, MD from NPA’s Board**, will share the next presentation.

Mary Carol: We’ll cover an overview of the NPA/AMSA collaboration, the AMSA role, the NPA contribution, and discuss what we feel are the most salient lessons learned. NPA has a small but growing presence in Boston, and AMSA has a large and well-organized presence. We tapped into our two organization’s historical relations, so we were able to provide a strong provider voice against conflict of interest to the Legislature. David has been involved in this work since the initial phase.

David: I will highlight the potential for doctors and medical students to cooperate with consumer advocacy groups to protect the interests of our patients. AMSA has worked on issues of conflict of interest (COI) in medicine for more than a decade. Our PharmFree campaign, which I currently chair, has worked since 2002 to promote evidence-based medicine, access to affordable medicine, and public access to medical information. Since 2007, AMSA has gathered information on medical schools’ policies on COI and publish them at AMSAScorecard.org.

Interest in the gift ban has been strong in the medical community for years. I want to focus on two moments during the budget discussion and the post-budget regulatory period, including the policy

goals we had in mind, the decision-makers we targeted, our tactics and some of the outcomes. I hope these are interesting case studies and illustrate opportunities for collaboration.

In April, our policy goal was to preserve the gift ban in the face of efforts for total repeal. The major decision-makers were the legislators. We engaged legislative leaders, together with the MRC, and put together a sign-on letter from 130 providers, representing all 4 medical centers, calling for full preservation of the gift ban. We worked with HCFA to deliver the letter personally to the legislators, and another tactic was a call-in campaign with reports from people as to what they heard. The outcome was a partial repeal, not what we had hoped for, with a charge to the Dept. of Public Health to define “modest.” We had learned that our advocacy efforts could garner significant press attention, including from the *American Medical News* (more independent and able to be more objective than the AMA, which was the basis for the MMA position), as well as from local press, and received an official response from Gov. Patrick’s office which illustrated, what we believed, were a misconception of the ethical standards in the medical profession.

For the regulatory stage, the decision-makers were the Dept of Public Health and the Public Health Council, so we wanted to appeal to them to define “modest,” ban “drunk learning,” and require adequate reporting. We were working with NPA by then, so our tactics were more robust, and we organized another sign-on letter. With HCFA’s help, we bussed more than a dozen medical students to deliver the letter in person to the Governor’s Office, wearing their white coats, with some great props. We carried martini glasses and stuffed lobsters on plates signifying the wining and dining of doctors, and held a large sign with a lobster with a hash thru it. We got good press coverage. We submitted written testimony, in collaboration with national AMSA, and also had independent testimony from local medical students and physicians. The national president of AMSA flew up to testify in person at the Department of Public Health hearing.

Key lessons – Despite not getting the outcome we had hoped for, the door is left open for further progress. I want to highlight that it was the power of collaboration between medical students and doctors working together that made a provider voice possible, and working with the consumer organizations helped us target the key legislators.

Mary Carol – The NPA collaborated with the sign-on letter and the official commentary calling for a ban on alcohol, a dollar limit on meal expenditures to be matched to the federal regulations. We can’t say we won at this point, but David’s point is well taken that as provider groups and the coalition we established ourselves as important voices at the table as the regulations are implemented and in the continuing conversations with the agencies and legislators involved. We did win one important concession in terms of the data collection required.

As to lessons learned, it is more rewarding from a membership perspective to organize a campaign with a strong existing core membership. Legislative timelines are so pressing that for NPA, partnering with an organization like AMSA that has a strong membership base, was critical to raising a successful voice. The political context in which the regulatory process was going on was important, especially in light of the fact that there were different targets from the first stage of the effort. The Department of Public Health Committee of Public Health is chaired by the Commissioner of Public Health. The Commissioner was not in a strong position to advocate for strong regulations because he was stepping down from his job in the wake of the MA compound drug pharmacy scandal which led to meningitis infections. The Governor seemed to have already decided how he was going to advise this body to act. There didn’t seem to be a lot of ways we could influence him because he was concerned about seeming to be a pro-industry politician. However, we raised awareness and brought ourselves to the table as important voices in this debate. This will be very useful when the Physicians’ Payment Sunshine Act is implemented as part of the ACA in the future.

David: A few key take-homes I want to offer. (1) It is important to identify the space where the physician voice can make a difference for our patients. We want public health to focus on the public. There is a tension between the recommendations of the AMA Council on Ethical Affairs, the Association of American Medical Colleges and the Institute of Medicine. Here we took the ethical high ground and identified the space we needed to fill. If we don't speak up, other voices will speak up and sometimes are very conflicted in terms of who they represent. (2) Multiple tools for physician advocacy are available, such as Dr Ryan tweeting this right now. The public delivery of the letters really was important, garnered press coverage and energized the medical student base of AMSA. (3) This story really illustrates that there is space for effective collaboration between students, physician groups and consumer organizations, like HCFA.

Q: Why was this in a budget bill? Was there a savings or revenue associated with the bill?

Alyssa: It was put in a budget because the budget has to pass every year, so if you really want your bill to pass, this is a smart way to do it. It was in an "outside" section of the bill, not in the revenue portion, where a number of provisions that do not impact funding are included.

Q: Did you have a sense that the medical students and physicians were really aware of what was going on to try to weaken the law and how did you energize them to become involved?

David: It was not obvious to them that this was happening. There was another scandal going on regarding lab testing at the time, too, which was the focus of attention. Thanks to the signers of the first letter, we had a list of 130 students and doctors who were really interested in the topic. Also, we really worked to establish personal connections with students by coming back to campus – students lose connections after they go off into their 3rd and 4th year rotations and are no longer on campus, so we went back to campus in person to talk to students. Finally, we framed this as a way for students to affirm the values that brought us to medicine. We found it much more effective with students, based on AMSA's work, to frame this in terms of patient-centered values instead of the potential for physician bias, which can be somewhat off-putting. This allows us to reach a broader audience.

Mary Carol: We were able to use personal contacts and the existing networks of providers in the state, and used the initial communication to reach out to groups to provide updates and provide information on the impact of advocacy efforts.

Q: What is the likelihood that the law to recover the old version of the bill will work?

Alyssa: It's hard to tell. We don't expect the leadership in the Statehouse or the Administration to change, so it will be a challenge. However, we should not give up. AMSA and NPA did an outstanding job to organize the provider voice to weigh in and it resonated with people, including the legislators. Moving forward, it's important not to lose the momentum that we've built.

Mary Carol: It is an advantage that this work is couched in the work of a broader coalition that has a long range plan for what to do to promote COI policies.

Q: Do you see the partnerships that developed out of this campaign opening up opportunities to work on other issues together?

David: Definite yes! It is very inspirational for students to be able to work with advocacy groups like HCFA, so the more students see of civil society organizations, the more they will see how to collaborate with them in the future. It is also hugely inspirational for them to see physicians speaking out on these issues.

Q: How unusual is the MA Gift Ban Law?

Alyssa: It is the most comprehensive in the country. MN and VT have lesser restrictions on conduct around gifts, and some other states have laws on disclosure of payments from the pharmaceutical industry.

Rachel: As on many other health care issues, Massachusetts is a trail blazer. Our next Conflict-Free call will be in approximately two months – watch your email for the date and information. Recordings and notes of past calls are archived online at <http://npalliance.org/conflict-free/>. Again, for more information about NPA and this project, visit the NPA Unbranded Doctor website at: npalliance.org/conflict-free . For more information on the AMSA PharmFree Scorecard, visit <http://www.amsascorecard.org/>

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Participants from the following states were included on this call: CT, FL, MD, ME, NJ, NY, OH, PA, VA, WA

NPA is a proud partner in the Partnership to Advance Conflict-free Medical Education ([PACME](#)). This partnership and related materials were made possible by a grant from the state Attorney General Consumer and Prescriber Education Grant Program which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.