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Subject: supplement to 10/27 testimony

This is to supplement my brief testimony on October 27. To avoid unnecessary repetition I would like to concur -- with minor reservations -- with the views expressed by Ken Libertoff in his testimony that day.

I support requiring reporting of gifts of free drug samples by pharmaceutical companies and believe that it is crucial that the reported data be made public. The only potentially legitimate exception would appear to be free samples of controlled substances, the public reporting of which might conceivably put providers at risk of theft. On this point I think there is a need to study available evidence as to the actual degree of risk and whether it should trump disclosure. Excepting that concern, reporting would appear to be strongly in the public interest.

At the hearing I quoted from an October 2008 press release re: the settlement that 33 states, including Vermont, entered into with Eli Lilly to resolve litigation re: Zyprexa marketing:

<http://www.doj.state.wi.us/absolutenm/anmviewer.asp?a=866>

"Product Samples

- Only provide product samples of Zyprexa to a health care provider whose clinical practice is consistent with the product's current labeling"

Similar language is in individual settlements that other states have reached with Lilly. It appears that free samples can play a role in off label prescription, or why would such language be included? Rampant off label use and drug company promotion of off label use have been characteristic not only of Zyprexa but of other atypical neuroleptics, and other psychotropic drugs (e.g. Neurontin). Mandatory reporting of free samples would make it possible to begin to get a handle on where samples are going and whether they have helped to enable inappropriate prescriptions.

At the hearing I also alluded to Dr. Susan Wehry's 2006 testimony to the Corrections Oversight Committee. Excerpts from that testimony are below. Although the context was legislative concerns about psychotropic drug prescription in Vermont's incarceration facilities, Dr. Wehry made it clear that the disturbing prescribing practices she described had originated in the

Vermont community and were then carried over to Corrections. Her testimony was an indication that there are serious problems in how psychotropic drugs are being prescribed in Vermont. There have been other indications:

"For example, in 2007 Vermont's Medicaid program spent \$20 million for psychotropic medications for children and adolescents; Washington state spent \$9 million." -- Psychotropic Medications Workgroup for Child and Adolescent Mental Health Questions from October 29, 2008 Meeting (posted at <http://www.healthvermont.org/mh/boards/documents/cafumedwgquestions10-29-08.pdf>)

My point is not to directly attribute dubious prescription practices to free drug samples. Rather, it is to underscore that there is evidence of a problem, no clear way to analyze it and limited understanding of contributing factors -- including the role played by free samples. **Without some way to track sampling it is impossible to gauge its impact. Requiring reporting is a way to begin providing some objective data, instead of conflicting testimony.**

I also wanted to respond to something that the child and adolescent psychiatrist Dr. Neil Senior said in his testimony:

"The dilemma in rural Vermont is the only people providing education around medication -- and given that medication's the mainstay of health care -- the only people doing anything are the pharmaceutical companies... if there's less sampling, there'll be less education."

According to the Centers for Medicare and Medicaid Services, "[t]he bulk of promotional spending is for sampling, or giving free drug samples directly to physicians." (from: Health Care Industry Market Update: Pharmaceuticals; posted at <http://www.cms.hhs.gov/CapMarketUpdates/Downloads/hcimu11003.pdf>). Sampling is openly acknowledged by pharmaceutical manufacturers as promotional. **Mistaking marketing for education may account for over reliance on pharmaceutical interventions and reinforce the perception -- which tends to dominate psychiatric practice -- that drugs are the "mainstay of care."** And if genuine education is in such short supply in this rural state, that may account for the excessive influence of "educators" who are actually engaged in marketing.

I attended the public hearing primarily to listen. I found it particularly frustrating hearing contradictory assertions of fact from different witnesses concerning the economic status of people receiving free samples. If this article has not been cited in other testimony, please see Chimonas, S, Kassirer JP (2009), No More Free Drug Samples? PLoS Med 6 (5): e1000074. doi: 10.1371/journal.pmed.1000074 (posted at <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000074>).

I believe the Commission has already been provided by other witnesses with journal articles concerning the effect of free samples on prescription practices. Its task is to implement the section of Act 59 requiring a study of disclosure of drug samples -- not to re-debate S.48. The legislature had a basis for prohibiting or requiring reporting of gifts from pharmaceutical manufacturers to prescribers; why wouldn't that basis apply to gifts in the form of free samples? If there is a need to address, or at the very least, understand, the influence of marketing on prescription practices, then why should *the bulk of promotional spending* be exempt from reporting?

Thank you for considering my concerns.

Dr. Susan Wehry, Medical Director, Vermont Dept. of Corrections
Testimony before Joint Legislative Corrections Oversight Committee, August 17, 2006
(excerpts; transcribed from Legislative Council CDs.

One, Vermont has the highest percentage of inmates on psychotropic medication in the country. It has the highest number of inmates who receive more than one psychiatric medication in the country. In -- to put this, if you like numbers instead of trends, in July forty-six percent of our inmates were receiving psychotropic medications, compared to a national -- forty-six percent compared to a national average of ten percent. Our next nearest competitor is twenty-four percent.

Vermont is liberal in its utilization of medications for treating all conditions. It is particularly liberal in its utilization of psychotropic medications. It is not at all uncommon for an offender to come in on three, four, five or six medications for similar conditions. We've started the conversation all over for the last year with the docs from the designated agencies, trying to understand it. There has been on my part and theirs an effort to look in the literature to see what supports it. There's very little support for that kind of polypharmacy as it's known, the prescribing of medications, in the literature, and there is a handful of individuals who do seem to benefit from having multiple medications. They are definitely in the minority in like a strict clinical practice, and they are definitely in the majority in our communities, and now in Corrections.

.....

No one -- to the extent that we can tell -- has ever benefited from being on more than, let's say 30 milligrams -- 20 or thirty, I forget at the moment. We have a whole cadre of people who are on 40 milligrams. Without any clear explanation.

... so we're talking about prescribing practices that are in our community and then they're carried over in Corrections.

What it looks like is that -- and this is where I think that we have to really try to understand it -- the biggest -- the biggest problem area for us is in the area of these drugs called antipsychotic medications. Without a doubt. There are very specific and very narrow indications for those medications. However, there is a very common practice in medicine. It's called off-label uses, and it's when, you know, this drug has helped somebody with a particular condition that was never studied, let's say, so it's called an off-label use. And when somebody is suffering, doctors try a lot of different things and so there's a -- it is an acceptable medical practice of off-label use. It looks like about seventy-five to eighty percent of our use is off-label. And it is by offenders who are on them in the community.

.....

I will tell you that this particular drug Seroquel is one that when I was practicing geriatric psychiatry, was the -- one of the most over-prescribed in nursing homes. And it was frankly the direct result of a blitzkrieg by the makers of Seroquel, through the State of Vermont, in which they -- finding out they could no longer take doctors to dinner, took every nursing home to dinner. And -- and so when, then, people were having behavioral problems, it wasn't uncommon for somebody to recommend that they try Seroquel. We had a huge problem with it here, frankly.

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The community mental health center directors are -- are concerned. The medical directors are concerned about suggestions that they reconsider their use of polypharmacy and off-label indications.
