Senate Testimony 6/29/2005

Good morning Senators, I'm Beatrice Manning, one of the whistleblowers in the recent government settlement with Schering Plough resulting in a $50 million criminal fine and a $292 million civil penalty. I worked at Schering for slightly over five years (Spring 1997- Spring 2002). During the four final years of my employment I was a whistleblower. I have a doctorate in sociology and came to Schering Plough after having been academia and having had a 10-year career in public health. I also worked a short time as a consultant to another drug company and for a major insurer.

While at Schering Plough I was the manager of opportunity identification at a wholly-owned subsidiary, Integrated Therapeutics Group (ITG). Now I am a student at Andover Newton Theological School with a specialty in ethics.

Schering Plough used an intricate scheme to cheat Medicaid out of hundreds of millions, if not billions, of dollars. Schering Plough evaded its responsibility to charge the US government and its beneficiaries the lowest price it charged the private sector, i.e., the best price as required by federal law. Most of the scheme was carried out using the subsidiary, ITG, which in retrospect I believe was created specifically to commit fraud. The scheme, which centered on Schering's blockbuster drug Claritin, had three major prongs that served as "kick-backs" in disguise. These kick-backs resulted in Claritin actually costing many insurers and HMOs an equal amount or less compared to Allegra, its major competitor. The lower amount, however, was not reflected in Schering's calculation of best-price, which it is required to give to Medicaid and other government programs.

First, the subsidiary provided free or well-below-cost health management services to HMOs that put Claritin on formulary. These services were not provided to Medicaid clients, including Medicaid clients enrolled in those same HMOs. The value of these services was not included in the best-price calculation Schering used to establish Medicaid pricing. ITG would sign a contract with the HMO and this contract would be totally separate from the cash rebate contracts that Schering Plough, itself would sign with insurers. Medicaid auditors would review the rebate contracts with Schering Plough (not the subsidiary, ITG) and thus would never see the additional "kick-backs" Schering gave through its subsidiary. I invite your attention to Exhibit A, a draft memo from Linda Zhou, who was then head of Schering's Contracts and Pricing division. In this memo, she is making the "business case" for further investment into ITG's computing capacity. On page 3, under Roman numeral I, she states, "ITG's services complement and enhance Schering's pharmaceutical products and meaningfully differentiate them from the competition. Thus, they provide our primary means of implementing the strategy to *compete on a basis other than price."* On the next page under the section of "Increased Profitability" she indicates that this has allowed Schering to decrease its discounts (by which best-price is determined) from 23% to 17% and right above we see that Schering as early as 1989 was increasing its sales (net of any rebates) by over $50M per year as a result of these health management contracts. Also note that throughout this memo there is no indication that health plans are paying anything for these health management services. The return on investment is calculated in Table 2 by dividing increased sales of Schering drugs by ITG's operation expenses, showing a nearly 4:1 return on investment for Schering. In essence, ITG's health management services to for-profit HMOs and other health insurers was being financed by the higher prices Medicaid was paying for Claritin.

I invite your attention to Exhibit B, showing the relationship between ITG and Schering Plough. Roch Doliveux is both the CEO of ITG and the Sr. VP of Managed Care within the Schering organization; he reports directly to Raul Cesan, who was then the CEO of Schering laboratories. The subsidiary, ITG, was tied to Schering at the highest levels.

Beyond health management services ITG also used "partnership fees" in its relationships with Pharmaceutical Benefits Managers (PBMs), which are often used by HMOs and other insurers to manage the pharmacy benefits part of coverage packages. ITG would engage with PBMs, who had large data sets, to conduct analyses for developing pharmacy metrics to be used in treating respiratory patients. They would be analyses that Schering already knew the outcome of, e.g., better treatment of allergies leads to fewer office visits for upper respiratory infections, or, better treatment of allergies leads to decreased emergency room use and hospital admissions for asthma patients. I want to be specific here -- these analyses were real and the results were real and I believe they indicated appropriate treatment for patients, however, "partnership fees" to do such studies were well above their actual cost. As the fees increased significantly above costs (compared to what had been paid to consulting firms), I and others were asked by management to indicate that these fees appropriately reflected effort and value to ITG. When I and the others refused, were we "counseled" and questioned about our loyalty to the company.

I invite you to examine Exhibit C an internal document showing Schering-Plough's flow of pharmaceuticals and cash. Two points are important if you look at the bottom of this flow chart. "Schering-Plough provides the HMO with free or underpriced services (Health Management)" and, flowing to the right and up, "rebate check and partnership fees to PBMs." ITG was used for both of these activities and they would not appear on Schering's books which were audited by Medicaid.

Finally, Schering used a law designed to allow pharmaceutical companies to give drugs free or at nominal cost to entities such as public hospitals and inner-city and rural health clinics serving low- income populations without these "gifts" entering into the best-price calculation. Schering, however, used this provision to "give" nominally price drugs, which were off-patent and low profit to for-profit insurers, and HMOs to equalize the difference between the "price" of Claritin and the "price" of Allegra. The last page of Exhibit D shows an example of this calculation. I suggest closing this loop hole.

I want now to turn to some key points that may explain why this scheme and others like it could continue so long without detection. First, work was organized such that it was quite difficult for any one person to put together the entire scheme, unless one was working at the very top levels of the organization. The Medicaid pricing unit was located in an entirely different location, had no contact with ITG, and wouldn't have seen ITG contracts. Even within ITG, work was intentionally "silo'ed." I would have done outcomes analysis, showing for instance, that treating allergies results in fewer hospitalizations for asthma, and I might have presented these findings to HMOs and PBMs, but I wasn't involved in structuring the health management "deals" between ITG and those entities. In reality, we were doing good work -- ITG's health management programs continually won awards and were recognized by firms like JD Powers as top programs. The work I did was being presented at medical meetings and being published in refereed medical journals. Frankly, for the average person it's hard to believe that your good work is in reality nothing more than a bribe.

Secondly, I want to stress that this scheme did not result from public corruption or inadequate Medicaid auditing. In essence, two sets of books were being kept.

Third, HMOs were not innocent participants in this scheme. There were HMOs, e.g., some of the best rated by US News & World Report -- Harvard, Tufts, Kaiser who would not accept health management services as a trade for formulary access. Those honest HMOs were disadvantaged by this scheme, having either to develop their own, or purchase, health management programs.

Fourth, when the investigation got "hot" there were serious attempts to force the blame down. Two to three years into the investigation, we started getting "compliance training" and surveys and tests asking such questions as, "Do you know of any product purchase being contingent on any other product?" Interestingly none of the training or questionnaires addressed "best price," the major violation. At best they would say that "best price" issues should be referred to the legal department. This would essentially be the kiss of death for employees in the field – sales would not be made and much of field force salary was based on sales. The corporate culture was designed to encourage individuals not to question actions. Examples for me include "counseling" sessions with my boss, where I would be told things like, "Bea, your job is not to point out problems. Legal can do enough of that by itself. Your job is to come up with solutions."

Finally, I believe there is still a considerable lack of information regarding Qui Tam and how to file Qui Tam complaints. We heard about this mechanism from our lawyer, Neil Mullin, whom we had engaged because we were being retaliated against for siding with a secretary who was being sexually harassed by our boss. Not surprisingly, he had provided much of the brains behind this scheme and was being protected. Had it not been for Neil's knowledge of Qui Tam and his willingness to take on this case, it probably would not have been filed. I admire Senator Grassley's action after our settlement was announced, when he asked drug companies to make sure their employees are aware of this option. Another group that I also think is important to inform is labor lawyers. Based on our experience, when serious and well substantiated cases are not being addressed, there are often other issues going on within the organization.

I want to spend just a few moments on my experience using Qui Tam. First, I want to say I always advise people against taking action if they are just doing it for the money. The thought of some potential money some time will not get you through what will in all probability be years of investigation with minimal feedback about what is even going on. Drug companies have major resources to throw at such cases. Over the six years of our case, we estimate that Schering was spending at least $50,000/day on legal expenses. Individuals, the US Attorney's office, and private attorneys cannot match that monetary commitment. Those issues aside, I want to state publicly that I admire the persistence of the US attorneys, Margaret (Peg) Hutchenson and Marilyn May, who handled our case. Without their persistence and Neil

Mullin's, Steve Engelmyer's, and Imogene Hughes', I do not believe that this case would have had a successful conclusion. It is our impression that, at the federal level, Medicaid was not consistently helpful to the US attorney's office.

Despite the successful outcome of our case, I do have some regrets, which I think have policy implications. Nobody was held personally responsible for their actions. No executives were pursued either civilly or criminally. While our settlement was one of the largest Medicaid settlements ever, to some extent $350 million dollars plus legal expenses was the cost of doing business for Schering. While Claritin was still on patent there were several years where Schering collected revenue exceeding $2 billion per year from Claritin sales. To be a more serious deterrent, Qui Tam must result in higher settlements and executives must be held personally responsible. I respect Senator Grassley's bill to review settlements as a step in that direction.

Finally, I want to stress the importance of Qui Tam in decreasing fraud. The intricate bookkeeping, siloed work environment, and the use of subsidiaries have made it virtually impossible to catch fraud through auditing alone. I also think that government needs to consider more extreme administrative controls in dealing with drug companies such as fee schedules similar to those used in relation to doctors and hospitals. This industry has become arrogant, essentially lawless, and definitely amoral in regard to its dealings with government and for that matter, patients.

I thank you for inviting me to share my thoughts and experiences with you.