As I looked at the Federal Register notice for these two days, there was reference to the use of a computer kiosk and computer algorithm as an aid for helping consumers with self selection. We thought it would be helpful to let participants visualize what that looks like, by showing a prototype that GSK had developed with the idea of using technology to assist consumers with appropriate self selection.

A potential problem that we get into with some of the more complex Rx to OTC switches is that there is a lot of information within the ‘Drug Facts’. There are multiple headings within the Drug Facts that have multiple elements defining what is appropriate for self selection and/or proper use of the product. It is placed in multiple locations and the flow sometimes can be confusing for consumers. It can be a lot of information to digest for the individuals who want to use the product. The potential benefit of some kind of interactive system, in this case a computer algorithm, is that you can present information in a more logical format for the question that you are trying to answer. This can be done in a step by step process and it can provide consumers with recommendations based on their responses to individual questions. It also provides the opportunity to ‘strip out’ elements of the label, and just focus on those elements that relate to, for instance, self selection.

We wanted to pick a drug to use as a prototype, and we selected an OTC statin for cholesterol reduction, which was a potential candidate for Rx to OTC switch. It was an ideal prototype because it had a lot of elements that define appropriate self selection. Those elements include gender, age, family history, current health status, and certain risk factors. So, it was a great example to look at, to build an algorithm that incorporates those complex issues associated with appropriate selection, to find out whether or not it makes it easier to present the information and get a response back.

Shown is the draft label for Mevacor, back in 2007. We based this on the Drug Facts information that would be present on the carton at the shelf. The consumer has to read and understand all the information, process it, and then make a product selection on that basis. This is the example of what was on the carton label. You can see the information starts on the front of the carton in terms of gender and age, as a factor for self selection. There are also the criteria that individuals first try to address their cholesterol with a healthy diet and exercise. Along with prior medical history, trying to resolve cholesterol with appropriate diet and exercise,
having the appropriate cholesterol range, together creates an algorithm which defines the circumstances of maximum benefit for the use of the product. Although very cleverly put together in terms of a visual algorithm within the carton, there is a lot of information here.

So, what we have done with this demonstration, is to break down the label into nine elements that are the basis of self selection, including gender, age, diet, and drug interactions, and run this through this kiosk.

So, step by step, going through the elements of the algorithm, I am going to run through it quickly twice, to show both correct and incorrect responses.

So, let us assume I am a male, 45 and older, and I have had a fasting cholesterol test in the past 12 months. I answer ‘yes’.

I know my LDL score, and it is between 130 and 170.

Have I tried diet and exercise? It is important to do those things first, so my answer will be a yes.

Next is a listing of the heart disease risk factors. So, I can pick whether heart disease runs in my family. The computer screen was also designed so that some educational elements can be incorporated. If we click on the box that says, ‘What is heart disease’, there is the ability with this technology to incorporate educational information within the algorithm itself, or elsewhere in the system. So, if there are definitions there that may not be clear, we can imbed definitions within the algorithm, to help clarify, and therefore help consumers respond to the questions.

The next screen lists other conditions that would make an individual not appropriate for the product. So, I will say ‘None of the above’ for this one.
The next screen lists drug interactions that would result in a recommendation not to use the product based on these conditions. So again, I will say ‘None of the above’ here.

On that basis, filling out the algorithm the way I did, the computer came back with a recommendation the product is right for me.

So now we will restart, and go through it again to illustrate a negative response.

I will say male again, 45 and older. I will say no to the question of having a fasting cholesterol test, and that I therefore do not know my score. Going through the rest of the screens with responses not consistent with the algorithm, I will get a recommendation against use of the product based on the way that I filled out the information.

The way this program was designed, we go through all the criteria and provide a final recommendation. It could have been designed so that the first time someone hit a wrong response there would be a detailed explanation as to why it was an inappropriate response.

This is very simple technology, providing a very simple way to look at the information and make it a little bit more interactive with the consumer. They can respond and with their information they get a recommendation personalized for them. We designed this on the basis of a kiosk, but, as mentioned previously, there is no reason why an individual could not run this same algorithm from a home computer, or in the aisle of the store using a Smartphone. The QR codes, boxes, black and white barcodes, could also be used with a Smartphone, in a retail setting, to link to a website that can run the algorithm.

This algorithm was designed to aid with self selection. There is no reason that you could not also imbed a similar algorithm to assist with repurchase. For example, ask questions of the consumer about the level of efficacy response, and about the potential for an emerging drug interaction with the use of the product. So, both an initial purchase algorithm and a repurchase algorithm are possible. There is a lot of flexibility in this very simple concept.

If you look on the back of every OTC product, there is a 1-800 number. Simple technology like a link from an app on a smartphone to a 1-800 number could be helpful if a consumer has specific questions about a product and wants to talk to a real person. Simple systems like a 1-800 line that are in place within the major companies may provide back up technology solutions that can be very beneficial for consumers.