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FDA MARCH 22-23, 2012 HEARING ON RX TO OTC SWITCH - AN HISTORICAL PERSPECTIVE TO INFORM FUTURE DIRECTIONS

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I first want to thank the committee and the organizers of these hearings. The origins of these hearings go back to a series of discussions we have had with FDA over several years. Most recently, about a year ago, we began the dialogue that led to these past two days. I especially want to thank the FDA for putting this together; the excellent set of presentations, the technology fair we had in this room in December, and Charley Ganley and Janet Woodcock for having the overall interest in pushing this forward.

I struggled deciding whether or not I was going to request to speak at this public hearing. For the last two days I sat twitching in my seat at some of the remarks being made and some of the really good suggestions and overall questions, not all of which were clearly answered. So maybe I can provide some help in that with my perspective.

I have worked in switch for near 20 years, and over 10 of those years were spent working on the switch of a statin, Mevacor. I have some scars to show for it, but maybe if there is such a thing as a Purple Heart Medal for switch, I might have earned one. The story on the statin switch is just an example I would like to provide, because I really am looking forward into the future rather than dwelling on the past. However, the lessons learned are important.

We worked on the statin switch for a long time, starting in 1997. At our first advisory committee in 2000 we debated whether or not we could tie the 10mg dose to the risk reduction seen in the AFCAPS cardiovascular outcomes study in primary prevention[1]. Ultimately, the FDA advised us to raise the dose to 20mg, and, over several years of work, we successfully answered the questions, as endorsed by the second advisory committee in 2005, of efficacy, safety, long-term use, the benefit that would be seen in terms of cardiovascular outcomes and the in-home use by consumers in the one-year Actual Use study, CUSTOM[2]. But the one part of the code that we were unable to crack was in successfully directing consumers to properly self-select.

We worked with Charley Ganley and Andrea Leonard-Segal and others in the OTC group at FDA to come up with novel ways to address the self-selection part of the equation, and get us to a place where we could be confident that consumers would understand what it takes to approximate the Framingham cardiovascular risk score for themselves.

Dr. Leonard-Segal might remember the prototype Mevacor carton with the 'selection wheels' where consumers had to line up their wheels to get all blue sections on the top, indicating that they were appropriate to use the product.

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The problem we ran into was that the agency was unclear on how they could actually regulate those self-selection aids, what we are now calling the 'conditions of safe use' that have been part of today's discussion. So we were advised to go ahead and develop the Mevacor OTC label using a standard Drug Facts approach. You saw some of the elements that we used to get creative within the Drug Facts paradigm in the presentation yesterday by David Schifkovitz of GSK. Although we probably came close to getting to a sort of 'sweet spot' with the right consumers wanting to use the product, we did not get all the way there, especially with the specifics of the label and the exact elements of age, lipid levels, and cardiovascular risk factors.

So at the third advisory committee hearing in 2007, we voluntarily committed to have these other special aids available to consumers in the marketplace, to drive better self-selection decisions. However, when the committee asked, 'Can you, FDA, make the sponsor do these things? Can you enforce these in the marketplace such that generics coming later must do the same thing?', the answer was no. The comfort level of the committee, and I think of the FDA in general, was reduced as long as they could not enforce these extra voluntary measures that the sponsor was willing to undertake. So there was no way the switch could be approved with just the pure Drug Facts labeling alone. That is the history. It is behind us now and we learned a lot.

So let us look forward for a minute. The 'conditions of safe use' that we are describing today are technology based. They do not require a pharmacist as the gatekeeper. Consumers love pharmacists. Pharmacists play a tremendous role in the overall health care continuum, giving consumers the direct ability to have someone to ask for advice at the point of purchase. But pharmacists are not required for these systems to work. Thus, there are no new issues about liability, about cost, about training or about record keeping with regard to pharmacy practice. These conditions and systems can be enacted now on a case-by-case basis for products where this is appropriate. I would expect that, by and large, most switches can still be accomplished by the traditional open-shelf paradigm. But we are talking in this instance about some more complicated switches, with a possibly greater impact on public health, which may need these technological aids.

We in industry need two things from the FDA before we can invest in these types of products, and the research programs that are important to bring these to the marketplace. Number one, we need a clear regulatory framework that the conditions of safe use can be approved and enforced as part of safe labeling, and, if we do not use them according to terms of approval, the product is considered misbranded. Second, the studies that are required to validate these systems must be viewed as essential for exclusivity. Ideally, they should qualify for the three years of Hatch-Waxman exclusivity; but maybe more. The time, energy and resources invested into these sorts of programs may require additional exclusivity in order to be worth doing. We certainly would like at the bare minimum to have the three years provided by Hatch-Waxman. However, under current thinking, a self-selection study in and of itself does not qualify for protection unless the participants are actually dosed with medication, according to the current interpretation of Hatch-Waxman. So that is very important to us.

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Let us not allow the perceived complexities that have been raised here over the last few days to overshadow the basic simplicity of the 'conditions of safe use' paradigm. Consumers are ready and willing. The technology is here now. Give industry the pathway to bring innovation to the table. We have a chance to impact public health on multiple fronts. Greater access is a given, but there are enormous education and self-support opportunities that these programs can bring. We have the ability, as you have heard, for enhanced pharmacovigilance tracking in ways that are not possible now. We will have better utilization of our precious health care resources and we will have a healthier and more productive America over the long term. It sounds grandiose, but I think we could get there if we start taking the first main steps that are needed to allow industry to start working toward this end. I heard Dr. Woodcock say, 'We need to seize the day.' I agree, the imperative is clear, let us make this happen. Thank you.

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