Announcement of OtisMed Settlement
Remarks as Prepared for U.S. Attorney Paul J. Fishman December 8, 2014

Good afternoon, and thank you for coming. I'm Paul Fishman, the U.S. Attorney for the District of New Jersey. With me are Jonathan Olin, the Deputy Assistant Attorney General for the Department's Civil Division in Washington; Tom O'Donnell, Special Agent in Charge of the New York Regional Office of the Inspector General for the Department of Health and Human Services; and Brian Rudolph, the Special Agent in Charge of the Washington Field Office of the FDA's Office of Criminal Investigations.

This morning, the OtisMed Corporation – which is now a division of Stryker – pleaded guilty to violating the criminal provisions of the Food, Drug, and Cosmetic Act. That felony guilty plea was the result of a lengthy investigation and is part of a comprehensive resolution that requires the company to pay more than $80 million for illegally marketing a surgical guide. In addition, OtisMed's former CEO, Charlie Chi, admitted to related crimes.

This case – and the guilty pleas – relate to the company's marketing of a surgical guide called the OtisKnee. That device, which you can see on the video that is an exhibit to the papers filed in court

this morning, is inserted into the knee of a patient needing a replacement. It attaches to the two bones – the fibula and the tibia that meet at the knee and shows the surgeon where to cut. Each guide is different, and is custom-built for the particular bone structure of the patient.

The trouble began in 2006 when OtisMed chose not to seek FDA approval for the device. Over the next three years, through the fall of 2009, OtisMed sold more than 18,000 OtisKnees without that approval. In total, those sales generated more than $27 million in revenue.

In the fall of 2008, while those sales were going on, OtisMed actually finally did file an application with the FDA. But on September 2, 2009, the FDA sent a letter denying that application. And the FDA was crystal clear: OtisMed had failed to demonstrate that the OtisKnee was appropriately safe and effective. In the language of the FDA, the OtisKnee was classified as a "significant risk device system," meaning it presented a potential for serious risk to the health, safety or welfare of patients.

Without that approval, the company was prohibited from marketing or distributing the device. Charlie Chi, who was the

president and CEO of OtisMed, understood exactly what that meant. And he was worried about the reputation of the company and its device if it stopped shipments to doctors who were planning to use the OtisKnee in upcoming knee replacement procedures. He also was worried about the company's future.

So what did he do? Against the explicit advice of the Board of Directors and the company's lawyers, Chi ordered his employees to send a mass shipment of the cutting guides to surgeons across the United States. Just one week after the FDA rejected the application, the company shipped 218 guides. The company didn't

tell the surgeons who received and then used them about the FDA's decision. That kind of flagrant disregard for the FDA – and for the safety of patients – cannot be ignored.

That explains the magnitude of today's settlement. The $80 million payment we are requiring of OtisMed, which is made up of criminal fines, forfeiture, and a civil penalty, is nearly three times the total revenue – not profit, but revenue – that OtisMed received from all the OtisKnees they ever sold. We insisted on this resolution to make the point that crimes of this kind literally do not pay.

In addition to the money, Stryker, the corporation that acquired OtisMed, will be required to adopt serious, forward-looking compliance measures to ensure something like this doesn't happen again.

But this isn't just about the company and it's not just about the money. Our office is committed to bringing criminal charges against individuals, particularly high ranking executives, whenever it's appropriate, even in – in fact, especially in – the context of large-scale corporate cases. And that's why Charlie Chi faces up to three years in prison when he is sentenced on March 18th on his guilty plea to three counts of

introducing adulterated medical devices into interstate commerce.

Working together, we in federal law enforcement are ensuring there are serious consequences for companies and individuals who put their profits ahead of the FDA's commitment to keep us safe. Corporations don't get to substitute their judgment for that of the experts.

I want to thank our partners in the Justice Department's Civil Division; the FDA's Office of Criminal Investigations and Office of Chief Counsel; and the Health and Human Services Office of Inspector General for their dedication to this investigation and this area of

enforcement. I also want acknowledge the two Assistant U.S. Attorneys who led the investigation for us – Jake Elberg, the Chief of my Office's Healthcare and Government Fraud Unit, and Charles Graybow, together with Ross Goldstein of the Department's Civil Division.

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Now I'd like to introduce Jonathan Olin, Deputy Assistant Attorney General from the Department's Civil Division in Washington.

Tom O'Donnell

Brian Rudolph

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Before we open the floor, I just want to add a couple of thoughts.

It is vital that products like the OtisKnee are subjected to the appropriate level of scrutiny. Patients seeking medical care are vulnerable; they are often afraid, and in pain. They should be able to trust their doctors. And they should be entitled to trust that the devices their doctors are using are safe, effective, tested, and approved. OtisMed and Charlie Chi betrayed that trust.

This is the latest in a string of significant corporate prosecutions in this District. Corporations and individuals have paid more than $620 million in health care and government fraud cases since I became U.S. Attorney. Corporations have pled guilty and agreed to substantial internal reforms. And we have convicted more than 50 doctors, nurses and physician assistants – as well as a number of individuals who falsely claimed to be medical professionals. As long as there are those who are willing to abuse our health care system for illegal profit, we will be there to protect patients and their families who deserve better.

We’re happy to take your questions.