We stand behind the safety of our devices, which have benefited millions of patients who continue to find relief from the debilitating conditions that necessitated them to undergo surgery.

We meet, and strive to exceed, required regulatory standards, and our devices (such as those mentioned in your letter) are subject to careful reviews by multiple regulatory bodies around the world. Once made available for use, we continue to analyze information such as clinical data and adverse event reports to track its performance.

Still, all surgical procedures and implanted medical devices involve risks, and a discussion between a doctor and patient to weigh those risks versus the benefits is a critically important part of any pre-surgical process.

Hip replacement devices have been available in the U.S. for more than 50 years, and have a long clinical track record of helping to relieve pain and restore mobility for patients. Like almost every medical device, hip replacements have had many changes in features and materials over that time. The FDA has determined that these changes should be cleared through the 510(k) review process because laboratory tests and other information comparing the new device to something already being sold can show whether the new device gives rise to new concerns about safety or effectiveness. Almost every hip replacement device sold today has been cleared through this process, supported by extensive laboratory testing, and hip replacement is regarded as one of the most successful surgeries in the world. This track record demonstrates that this regulatory framework has worked very well, allowing patients prompt access to advances in the technology they need.

We appreciate the opportunity to provide information and address inaccuracies in the facts and underlying premises outlined in your questions about these complex topics, including your summary of the regulatory background of these devices, which is not complete or fully accurate. In addition to this letter, please refer to our website, www.understandingultamet.com, which provides additional detailed information that addresses many of the topics raised in your letter.

The FDA has been extensively involved with metal-on-metal devices. After careful consideration, the FDA decided in the mid to late 1990s that metal-on-metal hip replacements should be cleared through the 510(k) pathway. FDA scientists reviewed the scientific and medical literature, attended worldwide meetings of experts and consulted with independent researchers in reaching this decision, as well as decisions on its ongoing regulatory activities for this product class. The 510(k) process continues to be used to review 95% of all medical devices.

The cobalt-chrome metal alloy used in metal-on-metal hip replacements had been used in many types of medical devices, including in hip replacements, for decades and had been shown to be one of the very few materials with the necessary strength, endurance and
compatibility. Modern metal-on-metal hips had been used in Europe with excellent results since 1988 and were first cleared for sale in the U.S. by the FDA in 1999. Before any individual manufacturer (including DePuy) could begin selling a metal-on-metal hip, the FDA required the manufacturer to provide clinical data supporting the safety and efficacy of one of their own device designs. Subsequent devices from that same manufacturer that the FDA concluded were substantially similar to the previously cleared metal-on-metal device could rely upon that earlier clinical data plus laboratory testing of the new device.

Please note that contrary to your letter, the ULTIMA® Metal-on-Metal Acetabular Cup was the subject of a clinical study and did also undergo extensive laboratory testing. Those data were submitted to the FDA before ULTIMA was cleared for sale. ULTIMA Cup sales were discontinued in 2007 for commercial reasons, since PINNACLE® ULTAMET and ASR XL were both available by then. The ULTIMA Cup was not recalled.

Some have incorrectly claimed that if metal-on-metal hip replacements had gone through the different FDA’s Pre-Market Approval (“PMA”) pathway, they would not have been approved for sale. In fact, metal-on-metal resurfacing products (a very similar alternative treatment to total hip replacement) did go through the PMA process and were approved for sale by FDA. Further, the DePuy ULTAMET metal-on-metal device was used in two FDA supervised clinical studies for other products that went through the PMA process and demonstrated excellent results in both clinical studies. Tens of thousands of patients have benefited from having metal-on-metal hip replacements and continue after 10 years or more to enjoy increased mobility and relief from pain.

To clarify the dates of regulatory clearances, the U.S. FDA cleared ULTAMET for sale in 2000, followed by the ASR XL in 2005 (your letter mistakenly states 2008). After ASR XL and ULTAMET implants came on the market, DePuy continued studying and closely monitoring how the devices were performing, as we do with all our devices.

It is the company’s practice to monitor the totality of the data from a variety of sources, including joint registries, published literature, company-sponsored clinical trials, internal complaints data and external clinical research reports. Our ongoing monitoring of clinical data for ULTAMET Metal-on-Metal has continued to show a track record of reducing pain and restoring mobility for patients suffering from chronic hip pain.

As to your questions about product use among surgeons who contribute to the design of products, the Company has adopted rigorous policies and procedures to help ensure the integrity of the relationship with doctors, and that patients’ needs come first. These guidelines are based on industry codes of conduct as well as the legal, regulatory and professional requirements of the countries where we do business, and are outlined in more detail on our web site, Responsible Interaction with Health Care Professionals.

It is in the best interests of patients to have surgeons who implant hip replacement products involved in designing them and the associated surgical instruments. These surgeons have innovative ideas and extensive “know how” to contribute to product development. Compensation for these contributions may involve the payment of a royalty, which is often
based on product sales for a pre-determined period. This means that if a product helps many patients – as the PINNACLE product line has – the royalties that are paid will be much greater than for products which do not achieve these results.

DePuy has rigorous compliance policies and procedures governing royalty arrangements. Collaboration with surgeons has been an integral part of the orthopaedics industry for many years, as the intellectual property for orthopaedic products, which forms the basis for any royalty payment, is often originated or owned by the physician. Importantly, royalties are not paid on any products implanted in patients by the royalty-earning surgeon, the surgeon’s partners, or at the surgeon’s hospital.

In developing metal-on-metal hip replacements, DePuy consulted with leading scientists and practicing orthopaedic surgeons from around the world. Their guidance on the issues and concerns they were facing with then-available bearing options and surgical instruments, plus their insights regarding new technologies lead to new designs that gave surgeons and patients new, additional treatment options.

Patients who believe they have legal claims against the company caused by an ULTAMET implant have exercised their rights to bring lawsuits in the U.S. and abroad. Four ULTAMET Metal-on-Metal jury trials have occurred in the United States. Of those four, one was decided in favor of the Company and three were decided in favor of plaintiffs. The first plaintiffs’ verdict was reversed on appeal; the other two cases are pending further court review.

Another case decided in May 2018 in the UK, addressed claims of more than 300 patients in a group litigation claiming that DePuy’s ULTAMET® Metal-on-Metal Articulation was defective. Following months of trial, the Court rejected these claims and entered a judgment in favor of the Company. The Court ruled that ULTAMET met the standard of safety under the Consumer Protection Act and performed as well or better than other prostheses that were on the market at the time ULTAMET was introduced. In fact, among other things, the judgement described ULTAMET as “a well-designed product with many positive engineering features”. The court found that although a metal-on-metal product would, by its very nature, produce metal wear debris – which in turn might cause an adverse reaction in some patients – that was not in itself a defect for the purposes of the Act.

A different metal-on-metal implant, the ASR Hip System, was voluntarily recalled by DePuy in every market where it was sold in August 2010. The recall was the result of the Company receiving new information from the UK National Joint Registry (NJR) as part of the company’s ongoing surveillance of post-market performance data for the ASR Hip System. After reviewing these data, which were not in line with data previously reported in that registry, DePuy decided it was in the best interests of patients to voluntarily recall the ASR Hip System. Prior to August 2010, the totality of the data available to the company showed ASR was performing consistent with the class of large diameter monoblock metal-on-metal hip implants.
While patient privacy protection laws prevent medical device companies from having direct access to the names and contact information of patients who receive their products, hospitals and surgeons are informed of the recall and have access to this information, along with details of the implants their patients received. This is true in India and in every other country in the world.

To respond to your question about the regulatory notifications in India, note that we immediately informed the Drugs Controller General of India (DCGI) about the voluntary recall and have kept the DCGI informed of all key actions. An Urgent Field Safety Notice dated 24 August 2010 was sent to surgeons and hospitals by the Company informing them about the voluntary recall. The Company also set up a public website about the recall, ran advertisements and hired independent third-party firms to assist surgeons in patient outreach to notify ASR patients of the recall. Crawford, which is the third-party administrator for the ASR Reimbursement Program, was not involved in the process of notifying patients about the recall.

The Company has voluntarily compensated ASR patients by taking the unprecedented step of addressing the costs of recall-related medical care and associated out-of-pocket expenses and lost wages through the ASR Reimbursement Program. The Program is available to all patients globally, and participating in the program does not require patients to waive their legal rights to pursue a claim against the Company.

If necessary, the legal system is available to pursue further compensation claims as it enables the specific facts of a case to be carefully examined, and a determination of liability and the level of compensation, if any, to be made based on local laws and the facts of each specific case. Some ASR patients who sought relief from the legal system in their local countries have been awarded compensation by the courts, consistent with those countries’ legal systems.