CHIRON

Statement Presented To

House Committee on Government Reform

United States House of Representatives

By Howard Pien

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Introduction

Mr. Chairman, Members of the Committee: Thank you for the opportunity to submit a statement for the record to the House Government Reform Committee at today's hearing. I am Howard Pien, President and CEO of Chiron Corporation, a global biotechnology company headquartered in Emeryville, California, with 2003 revenues of $1.75 billion. Founded in California in 1981, Chiron is composed of three business units: BioPharmaceuticals, Blood Testing and Vaccines. Chiron is dedicated to research and innovation addressing global public health challenges.

We regret that we cannot attend the hearing in person today. We would welcome the opportunity to appear at a hearing when we have additional information regarding our discussions with the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom and the Food and Drug Administration (FDA). As we have from the beginning of this situation, Chiron intends to be open and transparent with you and Federal authorities regarding our manufacturing situation.

Over the last few days, Chiron has learned an extremely painful lesson that is particularly devastating to our company due to the public health consequences of our inability to deliver this important vaccine. Since its creation, Chiron's mission has been to address global public health challenges, and, in this instance, we are unable to deliver. Chiron is deeply saddened that, despite the hard work during the past six weeks of large numbers of people within the company, we are unable to help address the threat of influenza in the United States this season.

As of today, Chiron reaffirms its resolve to take all appropriate actions to discover how we can improve our operational and managerial procedures and to implement a program of change to ensure that we can expeditiously regain our license. Among the specifics are:

- Systematically examining our manufacturing capabilities, including quality control. Chiron will make the necessary investments to ensure that we meet the highest standards of Good Manufacturing Practices.
- Ensuring that, in addition to the routine inspections that our facilities undergo, we are in frequent contact with regulatory authorities to understand any concerns that may exist and address them proactively.
- Assessing our processes for communication with key public health stakeholders to identify any opportunities for enhancement.

Supply of Influenza Vaccine for the 2004-2005 Influenza Season

On August 26, Chiron Vaccines announced that in conducting final internal release procedures for our Fluvirin® influenza virus vaccine, our quality systems identified a small number of lots that did not meet product sterility specifications. This related to contamination with *Serratia marcescens*. Chiron therefore announced that we had delayed releasing any Fluvirin doses until completion of additional quality assurance tests, a process that was projected to delay release until early October. Recognizing the

public health implications of this projected delay, Chiron immediately began communicating with and informing key public health stakeholders, agencies and regulatory authorities, including the Centers for Disease Control and Prevention, the National Vaccine Program Office, the National Institutes for Health and Centers for Biologics Evaluation and Research, and the UK Department of Health. Chiron regularly provided updates on the status of our investigations to these public health stakeholders via weekly teleconferences and/or informal discussions.

On September 27, Chiron completed internal investigations, and the results were in line with our expectations that the variance was confined to the initial scope identified. On October 5, MHRA informed Chiron that the agency was temporarily suspending our manufacturer's license for Fluvirin with immediate effect for a period of three months on the grounds that Chiron had failed to conduct operations in accordance with Good Manufacturing Practice regulations of the United Kingdom. The order also prevented the release of any influenza vaccine produced in Liverpool for the 2004-2005 influenza season. The suspension means that Chiron will be unable to meet our previously stated expectation of delivering between 46 million and 48 million doses of Fluvirin to the U.S. market beginning in early October.

Chiron deeply and profoundly regrets our inability to meet our commitment to the United States due to the suspension of our manufacturer's license, and we understand and are distressed by the public health consequences that this might have.

Going forward, our primary objective is to ensure that we restore our ability as a reliable supplier of influenza vaccine to the United States and become a dependable partner to those who are battling to reduce the burden of influenza, a disease estimated to cause an average of approximately 36,000 deaths annually. The first step to accomplishing this goal is to ensure that we are in a position to supply influenza vaccine to the United States for the 2005-2006 influenza season and, if necessary, contribute to vaccine supply in the event of a pandemic.

In order to accomplish this Chiron's highest priority is to address the concerns raised by the MHRA in its letter of October 5. We have taken action to achieve this goal as rapidly as possible. On October 6, senior management representatives from Chiron Vaccines met with the MHRA and initiated a dialogue to better understand the agency's concerns about the Liverpool facility and how those concerns can be addressed. We hope this meeting will lead to a remediation plan that will permit the lifting of the suspension if in the MHRA's view the plan is successfully implemented.

It is of paramount importance that we focus our efforts on addressing the concerns of MHRA so that our manufacturing can be up and running in order to supply influenza vaccine to the United States for the next influenza season. The production cycle time for influenza vaccine is such that Chiron expects it will need to commence preparations for vaccine manufacture by March 2005 at the latest in order to supply vaccine by September 2005.

Prior to receipt of the letter from the MHRA on October 5, Chiron did not anticipate that the MHRA would temporarily suspend our manufacturer's license for Fluvirin. Chiron had completed internal investigations on September 27, and the results were in line with our expectations that the variance was confined to the initial scope identified. Chiron therefore expected to report our conclusions to the MHRA and, upon confirmation, proceed with releasing Fluvirin to the U.S. market in early October. Inspectors from the MHRA visited the Liverpool site between September 28 and 30. To facilitate their process, Chiron voluntarily complied with the MHRA's request dated September 24 that Chiron not release Fluvirin until the review was concluded. Chiron made CBER aware that we were awaiting completion of the MHRA process to release Fluvirin. The MHRA inspectors concluded their site visit by providing Chiron with informal written comments on Thursday, September 30. Chiron reviewed the informal written comments and addressed them in a written response sent to the MHRA on Monday, October 4. Chiron believed that we had addressed the findings raised by the inspectors and was therefore taken by surprise by the MHRA's conclusion communicated on October 5 that Chiron had failed to conduct our operations in accordance with Good Manufacturing Practice regulations.

We did not perceive that there was any indication from the MHRA prior to October 5, that the outcome of the MHRA review would be the suspension of our manufacturing license for Fluvirin. Chiron appreciates that the MHRA's decision was rooted in concern for assuring product safety, a concern Chiron completely shares.

Chiron is committed to maintaining open, effective and transparent communications with key public health stakeholders. Chiron did not at anytime mislead public health stakeholders or the public. Chiron had no reason to anticipate that the MHRA would have concerns sufficient to warrant suspension of our manufacturing license. The results of Chiron's internal investigations confirmed our belief that our product was safe. We deeply regret that Chiron did not anticipate that the MHRA would have come to the decision that it did. Throughout, Chiron communicated with public sector stakeholders at the earliest junction.

Chiron recognizes the public health consequences of our inability to supply vaccine and the significant efforts that the CDC, NVPO, National Influenza Vaccine Summit and health care workers in the public and private sector will need to devote to working through the shortage. Chiron apologizes unreservedly for our inability to meet our commitment to supply vaccine to the United States. Chiron is also grateful for the leadership role that the HHS and its umbrella agencies CDC, NVPO, NIH and CBER have immediately taken in responding to our announcement. Chiron pledges to provide whatever assistance it can as the challenges of this season are being addressed. In addition, Chiron will work tirelessly to address the concerns of the MHRA to be in a position to supply vaccine for next season.

Looking Towards the Future

In conclusion, it is a public health tragedy of substantial magnitude that there is an insufficient supply of influenza vaccine. We vow to assist the men and women of the Public Health Service as they handle the challenges of this season. Chiron respects the MHRA's decision and is determined to work closely in partnership to develop and implement a remediation plan over the next few months to address its concerns. Our primary concern at this time is to do whatever it will take to have the suspension lifted in time to be in a position to supply influenza vaccine to the United States for next season. This has been a painful experience for our company and we resolve to ensure that this does not occur in the future. We wish we had not been taken by surprise by the MHRA decision, but we were. We wish we had been able to anticipate MHRA's inclination earlier, but we were not.

Chiron remains committed to supplying influenza vaccine to the United States. We will make all of the necessary investments in people and processes to bring our Liverpool facility up to the highest standards of regulatory compliance. In the next few weeks we expect to clearly establish the remediation plan with MHRA. We will continue to invest in the development of cell culture production, the next generation of influenza vaccine production technology, in order to have a more reliable and robust production process. We will continue to support pandemic preparedness efforts through research and development of new vaccines.