WRITTEN TESTIMONY OF HOWARD L. DORFMAN

Before the

UNITED STATES SENATE SPECIAL COMMITTEE ON AGING

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Chairman Collins, Ranking Member McCaskill, and members of the committee. Before answering the committee's questions, I would like to provide context by sharing my thoughts on the current discussions involving the cost of prescription pharmaceuticals, and price increases by companies in the pharmaceutical industry. The opinions I provide to the committee today are my own and do not represent those of any present or former clients I have counseled during my thirty years as an in-house and outside counsel in the pharmaceutical industry. In addition, due to issues of attorney-client privilege, I must respectfully confine myself to my role as an executive and advisor on business and commercial issues.

From December 2014 until August 13, 2015, I served as Senior Vice President, General Counsel at Turing Pharmaceuticals, AG, a privately held Swiss-based pharmaceutical company with offices in New York City. At a point during 2015, Turing acquired the manufacturing and commercialization rights to a drug, Daraprim, from Impax Laboratories. Daraprim, the trade name for pyrimethamine, has been available since 1953, and is considered the "gold standard" and cornerstone in the treatment of toxoplasmosis, a parasitic disease that can be fatal in patient populations with compromised immune systems, as is the case with HIV and cancer. In the opinion of most experts, there is no adequate substitute drug for Daraprim.

Few patients suffer from toxoplasmosis. Drugs with such limited target populations developed by pharmaceutical companies, so-called "orphan drugs," may be priced higher than drugs with a wider potential market, because of research costs and limited revenue expectations.

Following its acquisition of Daraprim in August 2015, Turing announced an increase in the price of the drug from approximately $13.50 per pill to $750 per pill. Turing implemented another change by entering into an exclusive distribution agreement with a specialty pharmacy company, limiting access to the drug through the specialty distributor.

I and other members of the Turing management committee repeatedly raised business objections to these and other aspects of the commercialization plans under discussion in anticipation of the finalization of the acquisition of Daraprim, based on our belief that the proposed actions would have a severely negative impact on Turing's business and reputation. The objections against an immediate and precipitous rise in the cost of Daraprim included concern as to the availability of the drug for a particularly vulnerable and vocal HIV and AIDS patient community, the lack of any formal study protocol in place to implement research to develop a "next generation" toxoplasmosis therapy, and the failure to develop any of the educational materials for healthcare professionals and patients, all of which were announced as components of the rationale for an immediate price increase. We made these objections during management committee meetings attended by the senior executives of the company, including the Chief Commercial Officer, Nancy Retzlaff. In fact, Ms. Retzlaff shared these concerns in these meetings and in discussions with other members of the management committee in private discussions.

Pharmaceutical companies typically justify drug price increases, especially large rises, by expenditures such as research and development of the drug itself or a substitute, clinical trial work, or educational programs. In this instance, the price increase, as contemplated and subsequently announced, was not justified by any such actual expenditure.

Having referenced the retention of a specialty pharmacy for commercialization purposes upon the acquisition of Daraprim, it is important to understand how that closed distribution system plays a role in maximizing the returns on a drug such as Daraprim. Specialty pharmacies can play a crucial role in a program (often mandated by the FDA) to manage and minimize risks to patients. By creating a direct relationship between the specialty pharmacy and the patient and caregiver, the pharmaceutical manufacturer can have access to critical adverse event information in real time, as well as the ability to monitor utilization and maximize expedited delivery. But such a system can reduce, if not eliminate, the opportunity for a second generic entrant to furnish sufficient quantities of the drug to patients in order to complete the necessary bioequivalence studies required for FDA approval. In the case of Daraprim, the retention of a new specialty pharmacy distributor to carry on a closed distribution system was considered an integral part of the company's desire to block a generic entrant for at least three years.

The issue of drug prices continues to generate considerable debate. One reason for drug pricing can be found in the costs inherent in the development of a prescription drug, from lab through regulatory approval. In November 2014, the Tufts Center for the Study of Drug development estimated that cost to be $2.6 billion, a 145% increase, correcting for inflation, over the estimate made in 2003. Whether one accepts that figure at face value, it is recognized that

drug development is a costly venture with significant risks of failure before final marketing approval is granted. What has fueled the recent debate to a large extent has not been price increases per se, but the increase in prices for drugs developed decades earlier without either patent protection or the expenses of clinical trials.

In closing, I hope I have been able to provide useful background and context into the activities under examination by this committee.