UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MISSOURI

EASTERN DIVISION

In re: NUVARING PRODUCTS LIABILITY LITIGATION	)	4:08MD1964 RWS
	)	
	)	ALL CASES
	)	
	)	Honorable Rodney W. Sippel

DECLARATION OF D. BRUCE BURLINGTON, M.D.

I, D. Bruce Burlington, M.D., do affirm under penalty of perjury the following:

1. I make this declaration based on my own personal knowledge.

2. I am a medical doctor and consultant on medical product development and regulatory affairs. After completing fellowships in infectious disease and viral immunology, in 1983, I took a position as a Medical Officer in the United States Food and Drug Administration ("FDA") Center for Drugs and Biologics. In 1986, I became Director of the Division of Biological Investigational New Drugs at FDA's Center for Biologics Evaluation and Research ("CBER"). In 1988, I became Deputy Director of the Office of Drug Evaluation II in FDA's Center for Drug Evaluation and Research ("CDER"). In 1990, I became Acting Director of the Office of Generic Drugs at CDER. In 1992, I became the Acting Deputy Director of Medical Affairs at CDER. In 1993, I became Director of FDA's Center for Device and Radiological Health ("CDRH"), a position I held until 1999. In 1999, I joined Wyeth-Ayerst Research as

a Senior Vice President in Global Regulatory Affairs. I held various executive positions at Wyeth until 2007, at which time I began my consulting practice.

3. Based on the foregoing experience, I am familiar with FDA's regulatory scheme for medical products, including the roles of CDER and CDRH, and the function of different Offices, Divisions, and positions within those Centers. Since their respective creations, CDER has had primary responsibility for the regulation of drugs and CDRH has had primary responsibility for the regulation of medical devices.

4. Between 1993 and 1995, when I held the highest position in CDRH, I was the indirect supervisor for Suzanne Parisian, M.D., a Medical Officer who, during my tenure, worked initially within CDRH's Office of Health Affairs and subsequently within CDRH's Office of Device Evaluation.

5. I have reviewed the claims of Dr. Parisian about her experience during her years at CDRH as described in her expert report and deposition in this case. I find her claims of experience to over-state the depth of her experience, particularly with regard to the regulation of drugs. Having held management positions CDER, CDRH, CBER, and the older Center for Drugs and Biologics, I can state that employment at one Center does not provide substantial or in depth knowledge, skill, experience, or training on the regulatory requirements for medical products for which another Center is responsible. Dr. Parisian's claims of expertise in the regulation of drugs based on her work at CDRH are inconsistent with my experience and belief.

6. Medical officers and scientists, working in CDRH, in general, have limited involvement in the regulation of drugs, if any, and only then in a secondary role to

personnel at CDER, consulting on medical device specific, combination product, and cross product area applicable questions. As I recall, Dr. Parisian was no different. As a CDRH medical officer, she would not normally have been responsible for approving products regulated as drugs, approving drug labeling, revising drug labeling, leading interactions with sponsors of drug studies, evaluating pre-market or post-marketing submissions on drugs, or any of the other function of a Medical Officer or supervisory official within CDER. For products regulated as combination products of a medical device and a drug, if the lead Center was CDER, and she was assigned to the review, she would have had an advisory and consultative role for the medical device aspects of the combination product, but the responsibility for regulatory decisions and leading interactions with the sponsor would have been assigned to an official working in the lead Center, CDER.

7. Like others at her level in CDRH, Dr. Parisian also had limited decision-making authority for medical devices. She did not, to my knowledge, have authority to approve a Pre-Market Approval medical device, clear a 510(k) medical device, require labeling changes for a medical device, require a specific human study for a medical device, or take any adverse regulatory action against a medical device manufacturer based on her assessment of regulatory compliance. Although, she might have recommended such actions from a medical review perspective, the decision to take action or not would have been made by her supervisors', the Division Director, the Office Director, the Center Director or their delegated deputies.

8. Dr. Parisian's claims that she presided over 262 health risk assessments and reviewed "hundreds of marketing applications" are misleading. Not only would few if any of

these health risk assessments have related to drugs, but the majority of the assessments would have involved relatively minor issues that did not involve any significant direct risk to the health of patients. They would instead have involved deviations from, or inadequate documentation of adherence to, the requirements of current Good Manufacturing Practices for medial devices. Most of the marketing applications Dr. Parisian ever would have seen as part of the review team at CDRH would have been far smaller than applications for new drugs and involved comparatively limited supporting human studies. Even if a few of them were for combination drug and device products regulated by CDRH as the lead center, they would rarely, if ever, have had the extensive studies and required the comprehensive evaluation of clinical pharmacology routinely undertaken for new drugs. Most medical device marketing authorizations are through the 510(k) clearance process and normally have no clinical studies required. The more comprehensive applications for new types of devices are called Pre-Market Applications (PMA). They will normally have a small pilot study and a single supporting clinical study in contrast to the many, often a dozen of more, clinical studies usually submitted with New Drug marketing Applications (NDA). The medical and statistical report sections of PMAs are far smaller than those for NDAs. PMA review, correspondingly, typically involves less extensive and less complex statistical analysis than does NDA review. And PMAs receive less in depth medical review then NDAs as reflected in the far larger number of medical staff in CDER than in CDRH, as Dr. Parisian notes, at the time of her employment on the order of 300 to 10 respectively, (despite there being roughly comparable numbers of original PMAs in CDRH and NDAs for new molecules in

CDER). CDER's review of applications for new drugs is far more detailed and involves more consultative reviews than CDRH's review of PMAs.

9. The medical device labels, labeling, and marketing materials that Dr. Parisian would have reviewed during her tenure at CDRH follow different requirements, have different formats, and are not directly comparable to prescription drug labeling and marketing materials. There are separate regulatory schemes for the labeling and enforcement of labeling and promotional requirements for drugs and medical devices.

10. As such, the role of a CDRH Medical Officer in the tasks identified by Dr. Parisian in her report is distinctly different from the role of a CDER Medical Officer in conducting his or her required tasks.

11. In short, as Director of CDRH while Dr. Parisian worked there, I do not see how her time at CDRH provides her with significant expertise, knowledge, skill, experience, or training on the regulation of drugs, the development of drugs, or the labeling of drugs.

12. I have no affiliation with Merck, Organon, or Schering-Plough and no personal bias against Dr. Parisian based on my prior experience with her.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 14 November 2011.

D. Bruce Burlington, M.D.