



## DECLARATION OF JAMES R. MAJERLE

I, James R. Majerle, declare as follows:

1. I am the Vice President and Chief Financial Officer (“CFO”) of Medi-Flex, Inc. (“Medi-Flex”). I have worked for Medi-Flex as the CFO since 1985, which was the year the company was founded. As CFO, I manage Medi-Flex’s financial resources, assist with strategic planning, manage administrative matters, and secure financing. I am knowledgeable about Medi-Flex’s product lines, finances, marketing, competition, and the Food and Drug Administration (“FDA”) regulatory process in general. Before joining Medi-Flex, I was the corporate controller for a banking services company, and also served as a certified public accountant. I have a Bachelor of Science in accounting and business administration and a Master of Business Administration from the University of Kansas.

2. Medi-Flex is a small, privately owned company. A significant portion of Medi-Flex’s revenue is derived from two over-the-counter products containing the combination of active ingredients chlorhexidine gluconate 2% and isopropyl alcohol 70%. These products, which are delivered by topical sponge, are broad-spectrum antiseptics used for preparing a patient’s skin before surgery. Medi-Flex is the only company on the market with products approved by FDA containing this combination of active ingredients and strength.

3. Medi-Flex’s first generation product is ChloraPrep® One-Step (chlorhexidine gluconate 2% and isopropyl alcohol 70%). This product received marketing approval under New Drug Application No. (“NDA”) 20-832 on July 14, 2000 and is available in the following applicator volumes: 1.5 ml, 3.0 ml, and 10.5 ml. There are several patents directed to ChloraPrep® One-Step, which were submitted to FDA. However, there is no FDA marketing exclusivity period for this product.

4. Although ChloraPrep® One-Step is a very effective product, Medi-Flex developed a second product with several improvements. The second product is ChloraPrep® with Tint (chlorhexidine gluconate 2% and isopropyl alcohol 70%) in a 26 ml applicator volume. Importantly, ChloraPrep® with Tint contains an additional tint ingredient, FD&C Green No. 3. This tint colors the product so that the user may quickly determine previously treated areas. Furthermore, ChloraPrep® with Tint has an applicator volume of 26 ml, more than double the volume of the previous applicator. Currently, Medi-Flex is pursuing approval of a 10.5 ml applicator volume for its ChloraPrep® with Tint line.

5. Medi-Flex invested substantial resources to bring the innovations embodied in ChloraPrep® with Tint to market. FDA required Medi-Flex to conduct numerous clinical trials over several years to prove that ChloraPrep® with Tint is safe and effective. In particular, FDA was concerned that the tint ingredient could affect efficacy. Consequently, Medi-Flex invested about \$120,000 to perform a clinical trial demonstrating that the addition of a tint ingredient does not affect efficacy. FDA also required Medi-Flex to conduct several clinical trials establishing that the 26 ml volume is safe. Medi-Flex’s safety studies, which cost approximately \$75,000, conclusively demonstrated that the 26 ml volume is safe.

6. FDA approved ChloroPrep® with Tint in a 26 ml applicator volume on May 3, 2005. Due to the successful clinical trials involving the tint ingredient and increased applicator volume, ChloroPrep® with Tint received three years of FDA market exclusivity, which expires May 3, 2008. In addition, there are several patents directed to ChloroPrep® with Tint, including one patent specifically directed to the tint ingredient, U.S. Patent No. 6,729,786 (the “Tint Patent”).

7. It is my understanding that Cardinal Health, Inc. (“Cardinal”) is seeking approval of Abbreviated New Drug Application (“ANDA”) No. 77-271 for a generic version of ChloroPrep® with Tint despite Medi-Flex’s three-year market exclusivity period. On November 18, 2004, Cardinal submitted a Suitability Petition to the FDA seeking permission to file an ANDA for a generic product containing chlorhexidine gluconate 2% and isopropyl alcohol 70% with tint, FD&C Red. No. 40, in a 26 ml applicator volume. On September 13, 2005, Cardinal sent Medi-Flex a letter reporting that Cardinal submitted ANDA 77-271 for a generic chlorhexidine gluconate and isopropyl alcohol product. Although Cardinal appears to be seeking approval for a generic version of ChloroPrep® with Tint, Cardinal’s September 13<sup>th</sup> letter indicates that Cardinal’s ANDA relied on ChloroPrep® One-Step and included patent certifications for ChloroPrep® One-Step’s patents. Medi-Flex replied to Cardinal with a letter on September 19, 2005, and followed-up with several telephone calls to obtain more details about the facts and a resolution to the issues. Unfortunately, Cardinal has not cooperated and has provided no additional information. Rather, Cardinal simply sent a letter to Medi-Flex stating that Cardinal now withdrew its ANDA patent certifications.

8. Based on the available facts, it is my understanding that Cardinal’s ANDA 77-271 seeks to circumvent Medi-Flex’s three-year exclusivity and patents for ChloroPrep® with Tint, particularly the Tint Patent, by inappropriately relying on the untinted ChloroPrep® One-Step. Accordingly, Medi-Flex submitted Citizen Petition Docket No. 2005P-0458 (the “Citizen Petition”) on November 14, 2005 requesting that FDA: (1) refrain from approving Cardinal’s ANDA until Medi-Flex’s three-year market exclusivity period expires; and (2) require Cardinal to rely on ChloroPrep® with Tint and to provide certifications for the related patents.

9. It is also my understanding that final approval of Cardinal’s ANDA is imminent, and Medi-Flex is submitting this Petition for Stay of Action to request that FDA stay approval of Cardinal’s ANDA 77-271 until FDA rules on Medi-Flex’s Citizen Petition.

10. If FDA were to approve Cardinal’s ANDA and allow Cardinal to go to market during Medi-Flex’s exclusivity period, it would cause immediate and irreparable injury to Medi-Flex. Medi-Flex is a small company whose main products include its ChloroPrep® line, such as ChloroPrep® One-Step and ChloroPrep® with Tint. ChloroPrep® with Tint represents a significant part of Medi-Flex’s revenue and is growing rapidly. In fact, Medi-Flex anticipates that 59% of its growth in 2006 will be from the sale of ChloroPrep® with Tint. Based on the anticipated growth, Medi-Flex recently invested in a new 360,000 square foot manufacturing, packaging, and laboratory facility.

11. When Cardinal goes to market with a generic version of ChloroPrep® with Tint, Medi-Flex’s market position will likely collapse within a very short period of time. As stated in a recent Cardinal press release attached to this Petition for Stay of Action at Tab 3, Cardinal is

the leading provider of products and services supporting the health care industry. It has annual revenue of \$75 billion and employs over 55,000 people worldwide. Recently, Cardinal ranked 16<sup>th</sup> on the Fortune 500 list.

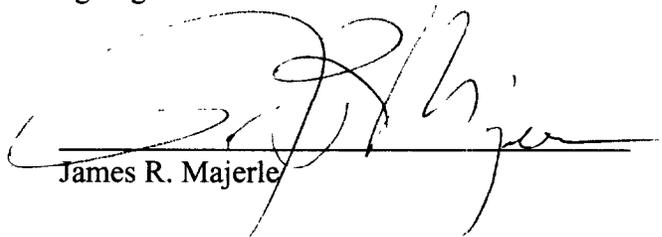
12. Importantly, Cardinal is a major distributor of Medi-Flex's ChloroPrep® with Tint. Approximately 34% of Medi-Flex's business is from sales of ChloroPrep® products by Cardinal. Thus, Cardinal already has an established marketing network for this product and directly controls a significant portion of Medi-Flex's sales. Cardinal's large size, marketing experience, and current business relationships with Medi-Flex's customers compound the injury to Medi-Flex and will allow Cardinal to take a significant share of the market extremely quickly. Once Cardinal goes to market, Medi-Flex predicts that it will lose all of Cardinal's business and potentially as much as 80% of its total projected business.

13. The generic competition from Cardinal will have a direct and incalculable impact on Medi-Flex's operational activities. Medi-Flex is relying on the anticipated demand and revenue from ChloroPrep® with Tint to support its new manufacturing facility, and a substantial reduction in market share would threaten that facility. Additionally, Medi-Flex would not be able to invest the lost revenue in new research and development activities, which are critical to the future success of Medi-Flex.

14. Furthermore, Medi-Flex's market exclusivity period provides unique opportunities that cannot be quantified or compensated financially. In addition to financial rewards, an exclusivity period allows a company to develop its business relationships and reputation, as well as establish brand loyalty, in a unique environment. Medi-Flex will lose the intangible benefits of exclusivity when its exclusivity period is violated and its major distributor, Cardinal, enters the market with a generic product. Unless FDA were to extend Medi-Flex's exclusivity period, there would be no adequate relief that could be provided to compensate Medi-Flex for its lost exclusivity period. To approve Cardinal's ANDA would cause irreparable injury to Medi-Flex and devastate this small company.

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

December 23, 2005  
Date

  
James R. Majerle