ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT
In the Matter of Integra LifeSciences Holdings Corporation and Johnson & Johnson
File No. 171-0084

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Integra LifeSciences Holdings Corporation ("Integra") and Johnson & Johnson designed to remedy the anticompetitive effects resulting from Integra's proposed purchase of certain assets of Johnson & Johnson's Codman Neuro ("Codman") division. The proposed Decision and Order ("Order") contained in the Consent Agreement requires the parties to divest all rights and assets to Natus Medical Incorporated ("Natus") related to Integra's intracranial pressure monitoring systems and fixed pressure valve shunt systems, as well as Codman's cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and dural grafts.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Asset Purchase Agreement signed on February 14, 2017, Integra

systems, non-antimicrobial external ventricular drainage catheters, fixed pressure valve shunt systems, and dural grafts. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

THE PARTIES

Integra, headquartered in Plainsboro, New Jersey, is a medical device company with worldwide operations and one of the largest surgical instrument suppliers in the United States.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

I. Intracranial Pressure Monitoring Systems

Intracranial pressure monitoring systems are used in intensive care units and operating rooms to measure pressure inside the skull, which can increase in the event of traumatic brain

part because even with such a price increase, antimicrobial external ventricular drainage catheters would still be considerably more expensive.

Integra and Codman account for 29% and 17% of the relevant market in the United States. The only other competitively significant firm is Medtronic, with a 51% share.

IV. Fixed Pressure Valve Shunt Systems

Shunts are the primary tool that neurosurgeons use to treat hydrocephalus, or excessive accumulation of cerebrospinal fluid. Shunt systems redirect excess cerebrospinal fluid from the brain or spinal cord to another area of the body, usually the abdomen, for reabsorption. Shunt systems consist of three components: a ventricular catheter inserted into the brain, a valve to regulate the flow of the fluid, and another catheter that is threaded to the location where the fluid is emptied. Once implanted, the one-way valve in the shunt system regulates the pressure in the brain by governing the amount and pressure of cerebrospinal fluid passing through the catheter.

There are two main types of hydrocephalus shunts: fixed pressure valve shunts and programmable valve shunts. Fixed pressure valve shunts allow cerebrospinal fluid to pass through the shunt only when the pressure has exceeded some predetermined setting, which medical providers cannot adjust once implanted without another surgery. The settings on a programmable valve shunt system, which is significantly more expensive, can be adjusted non-invasively using specially designed magnetic tools. An insufficient number of customers are likely to switch to programmable valve shunts to prevent a small but significant increase in the price of fixed pressure valve shunt systems.

Integra, Codman, and Medtronic are the only significant suppliers of fixed pressure valve shunt systems. Medtronic accounts for 55% of U.S. sales, and Integra follows at 23% share and Codman at 15% share. Aesculap and Sophysa hold small, fringe positions in the market and their products are not close substitutes to those of Integra and Codman.

V. Dural Grafts

Dural grafts are used to repair or replace a patient's dura mater, the thick membrane that

COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would cause substantial competitive harm in the relevant markets. The parties are the only significant suppliers of intracranial pressure monitoring systems in the U.S. market, and two of only three significant suppliers of cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and fixed pressure valve shunt systems in the United States. In the dural grafts market, a combined Integra/Codman would control the vast majority of the U.S. market and eliminate the close competition that exists between the parties today. Eliminating the head-to-head competition between Integra and Codman in all of these highly concentrated markets would allow the combined firm to exercise market power unilaterally, resulting in higher prices and reduced choice for customers in these markets.

ENTRY CONDITIONS

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money to design and develop an effective product, obtain FDA approval, and develop clinical history supporting the long-term efficacy of a product. A new entrant must also establish a sales and marketing infrastructure, have or develop a track record of service and support, and offer a robust line of neurosurgical products sufficient to convince potential customers of the viability of its new product offerings. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

THE CONSENT AGREEMENT

The proposed Consent Agreement and Order remedy the competitive concerns raised by the proposed Acquisition by requiring the parties to divest to Natus all assets and rights to research, develop, manufacture, market, and sell Integra's intracranial pressure monitoring systems and fixed pressure valve shunt systems, as well as Codman's cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and dural grafts.

resea-4(m)-6(p)4eror

epilepsy, head injury, tumors, Parkinson's, and sleep apnea. Natus is well positioned to restore the competition that otherwise would have been lost pursuant to the proposed Acquisition.

The parties must accomplish the divestitures and relinquish their rights to Natus no later than ten days after consummating the proposed Acquisition. If the Commission determines that Natus

qn3(s)-12(r)3(e)4(c)4(om)-24(l)-2(i)-(a)4,oN 3(w)2(i1)-2(t)-h4(t)-2(he)4Orr(t)-2(he)4(C3