MERGER ANTITRUST LAW

Steris/Synergy Health

(Full Set of Case Materials)

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Table of Contents

News Release

STERIS to Acquire Synergy Health for $1.9 Billion in Cash and Stock

Combination Creates a Global Leader in Infection Prevention and Sterilization

Allows Company to Further Invest in the U.S. and Accelerate International Growth

Conference Call with Senior Management at 8:30 a.m. EDT

MENTOR, OHIO AND SWINDON, U.K. - October 13, 2014 - STERIS Corporation (NYSE:STE) and Synergy Health, plc (LSE:SYR) today announced that STERIS is commencing a "recommended offer" under U.K. law to acquire Synergy in a cash and stock transaction valued at £19.50 ($31.35) per Synergy share, or a total of approximately $1.9 billion, based on STERIS's closing stock price of $56.38 per share on October 10, 2014.

Upon closing, the combined business (New STERIS) will have approximately $2.6 billion in annual revenues from over 60 countries, approximately 14,000 employees, and will bring together geographically complementary businesses. For medical device manufacturers, STERIS's Isomedix and Synergy's Applied Sterilization Technologies (AST) will create a leading global supplier to best serve medical device Customers with a network of 58 facilities covering 18 countries. For hospitals, the combination of STERIS's Infection Prevention and Services businesses with Synergy's Hospital Sterilization Services will strengthen the breadth and depth of the offering, accelerating the development of hospital sterilization outsourcing worldwide.

"Synergy's focus on achievement, accountability, integrity and innovation has enabled it to deliver remarkable growth for its Customers, people and shareholders since its founding," said Walt Rosebrough, President and CEO of STERIS Corporation. "We have great respect for the performance that Dr. Richard Steeves and his people have achieved, and look forward to welcoming them to the STERIS team. Together, we create a balanced portfolio of products and services that can be tailored to best serve the evolving needs of our global Customers. Once the transaction is completed, New STERIS will be a stronger global leader in infection prevention and sterilization, better-positioned to provide comprehensive solutions to medical device companies, pharma companies, and hospitals around the world."

"Synergy shares STERIS's commitment to growth for all of its Customers and partners, and this acquisition joins two great companies that share a similar set of values and a strategic vision," said Dr. Richard Steeves, CEO of Synergy Health. "The combined entity brings together the strengths of both businesses, allowing New STERIS to accomplish much more than either one of us could separately."

New STERIS will be incorporated in the U.K., while its operational and U.S. headquarters will remain in Mentor, Ohio. Walt Rosebrough, current President and CEO of STERIS, will be the CEO of New STERIS. Mr. Rosebrough, along with New STERIS CFO Michael Tokich and most members of senior management, will reside in Northeast Ohio.

STERIS plans to expand the New STERIS Board to thirteen members, of whom ten will be the current STERIS Directors and three will be current members of Synergy's Board of Directors. Included in the three new Directors

will be Synergy CEO, Dr. Richard Steeves. New STERIS is expected to be listed on the New York Stock Exchange under the ticker STE. The Boards of Directors of both companies have unanimously recommended the transaction.

Financial Highlights

STERIS has agreed to pay approximately $1.9 billion in cash and stock to acquire Synergy. In fiscal 2014, Synergy generated revenue of approximately $604 million and adjusted earnings before interest expense, income taxes, depreciation and amortization (EBITDA)[1] of approximately $161 million.

Upon completion of the transaction, each outstanding share of Synergy will be converted into the right to receive £4.39 ($7.06) in cash and 0.4308 of a share of New STERIS. The per-share consideration represents a premium of 39% to Synergy's closing stock price on October 10, 2014, the last trading day prior to the announcement, a 32% premium to the thirty trading day volume weighted average price, and a 27% premium to the 52-week high of Synergy. At closing, STERIS shareholders will exchange each share of stock they own in STERIS for one share of stock in New STERIS. STERIS shareholders will retain ownership of approximately 70% of New STERIS and Synergy shareholders will own approximately 30%. The transaction is expected to be taxable, for U.S. federal income tax purposes, to shareholders of STERIS.

The proposed transaction represents compelling value to both Synergy and STERIS shareholders through participation in the future growth prospects expected to result from the combination through their ownership of the combined company.

The transaction is not expected to impact STERIS's adjusted earnings per diluted share until closing. The transaction is anticipated to be significantly accretive to New STERIS's adjusted earnings per diluted share beginning in fiscal 2016.

The transaction is expected to result in total annual pre-tax cost savings of $30 million or more, which will be phased in 50% in fiscal year 2016 and 100% thereafter, from optimizing global back-office infrastructure, leveraging best-demonstrated practices across plants, in-sourcing consumables, and eliminating redundant public company costs. In addition, as a result of incorporating New STERIS in the U.K., STERIS anticipates that the effective tax rate of New STERIS, beginning in fiscal 2016, will be approximately 25%.

The transaction is subject to certain customary closing conditions, including approvals by STERIS and Synergy shareholders as well as regulatory approvals in the U.S. and U.K., and is anticipated to close by March 31, 2015. In conjunction with the transaction, STERIS obtained a 364-Day Bridge Credit Agreement. Bank of America Merrill Lynch, J.P. Morgan and KeyBank provided committed financing in conjunction with the transaction in the amount of approximately $1.6 billion.

Lazard acted as financial advisor and Wachtell, Lipton, Rose & Katz and Jones Day acted as legal advisors to STERIS in connection with the acquisition. Investec Bank plc acted as financial advisor and DLA Piper acted as legal counsel for Synergy.

For more information about the transaction, please go to www.steris.com/synergy (http://www.steris.com/synergy) beginning at 7:00 a.m. Eastern Daylight Time today.

Conference Call

STERIS and Synergy senior management will conduct a conference call and webcast to discuss this news

release today, October 13, 2014, at 8:30 a.m. Eastern Daylight Time (1:30 p.m. British Summer Time). The conference call can be heard live over the Internet at www.steris-ir.com (http://www.steris-ir.com) or via phone by dialing 1-800-369-8428 in the United States and Canada, or 1-773-799-3378 internationally, then referencing the password "STERIS".

For those unable to listen to the conference call live, a replay will be available beginning at 12:00 p.m. Eastern Daylight Time on October 13, 2014, either over the Internet at www.steris-ir.com (http://www.steris-ir.com) or via phone by calling 1-866-479-2462 in the United States and Canada, and 1-203-369-1537 internationally.

An overview presentation of the transaction call can also be viewed at www.steris-ir.com (http://www.steris-ir.com).

About STERIS

The mission of STERIS Corporation is to help our Customers create a healthier and safer world by providing innovative healthcare and life science product and service solutions around the globe. As a leading provider of infection prevention and other procedural products and services, the Company is focused primarily on healthcare, medical device, and pharmaceutical and research Customers. The Company offers its Customers a unique mix of innovative capital equipment products, such as sterilizers and surgical tables; connectivity solutions, such as operating room integration; consumable products, such as detergents, skin care products, and gastrointestinal endoscope accessories; services, including equipment installation and maintenance, microbial reduction of medical devices, instrument and scope repair solutions, and laboratory testing services.

STERIS is listed on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com (http://www.steris.com).

About Synergy

Synergy is a global leader in outsourced sterilization services for medical device manufacturers, hospitals and other industries, based in the United Kingdom (U.K.). The Company offers services that support their Customers' ability to improve the quality and efficiency of their activities, while reducing risks to their patients and clients. Synergy is listed on the London Stock Exchange under the symbol SYR. For more information, visit www.synergyhealthplc.com (http://www.synergyhealthplc.com).

(1) Synergy's financial statements are prepared in accordance with International Financial Reporting Standards as adopted for use in the European Union. Adjusted earnings before interest expense, income taxes, depreciation and amortization is defined by Synergy as operating profit excluding interest expense, income taxes, depreciation, amortization (EBITDA), non-recurring items and acquisition-related costs in the consolidated financial statements. Further information can be found in the Annual Report and Accounts 2014 of Synergy.

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Forward-Looking Statements

This document may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to Synergy or STERIS or its industry, products or activities that are intended to qualify for the protections afforded "forward-looking statements" under the Private Securities Litigation Reform Act of 1995 and other laws and regulations. Forward-looking statements speak only as to the date of this document and may be identified by the use of forward-looking terms such as "may," "will," "expects," "believes," "anticipates," "plans," "estimates," "projects," "targets," "forecasts," "outlook," "impact," "potential," "confidence," "improve," "optimistic," "deliver," "comfortable," "trend", and "seeks," or the negative of such terms or other variations on such terms or comparable terminology. Many important factors could cause actual results to differ materially from those in the forward-looking statements including, without limitation, disruption of production or supplies, changes in market conditions, political events, pending or future claims or litigation, competitive factors, technology advances, actions of regulatory agencies, and changes in laws, government regulations, labeling or product approvals or the application or interpretation thereof. Other risk factors are described herein and in STERIS and Synergy's other securities filings, including Item 1A of STERIS's Annual Report on Form 10-K for the year ended March 31, 2014 dated May 29, 2014 and in Synergy's annual report and accounts for the year ended 30 March 2014 (section headed "principal risks and uncertainties"). Many of these important factors are outside of STERIS's or Synergy's control. No assurances can be provided as to any result or the timing of any outcome regarding matters described herein or otherwise with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, cost reductions, business strategies, earnings or revenue trends or future financial results. References to products and the consent decree are summaries only and should not be considered the specific terms of the decree or product clearance or literature. Unless legally required, STERIS and Synergy do not undertake to update or revise any forward-looking statements even if events make clear that any projected results, express or implied, will not be realized. Other potential risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, (a) the receipt of approval of both STERIS's shareholders and Synergy's shareholders, (b) the regulatory approvals required for the transaction not being obtained on the terms expected or on the anticipated schedule, (c) the parties' ability to meet expectations regarding the timing, completion and accounting and tax treatments of the transaction, (d) the possibility that the parties may be unable to achieve expected synergies and operating efficiencies in connection with the transaction within the expected time-frames or at all and to successfully integrate Synergy's operations into those of STERIS, (e) the integration of Synergy's operations into those of STERIS being more difficult, time-consuming or costly than expected, (f) operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients or suppliers) being greater than expected following the transaction, (g) the retention of certain key employees of Synergy being difficult, (h) changes in tax laws or interpretations that could increase our consolidated tax liabilities, including, if the transaction is consummated, changes in tax laws that would result in New STERIS being treated as a domestic corporation for United States federal tax purposes, (i) the potential for increased pressure on pricing or costs that leads to erosion of profit margins, (j) the possibility that market demand will not develop for new technologies, products or applications or

services, or business initiatives will take longer, cost more or produce lower benefits than anticipated, (k) the possibility that application of or compliance with laws, court rulings, certifications, regulations, regulatory actions, including without limitation those relating to FDA warning notices or letters, government investigations, the outcome of any pending FDA requests, inspections or submissions, or other requirements or standards may delay, limit or prevent new product introductions, affect the production and marketing of existing products or services or otherwise affect Company performance, results, prospects or value, (l) the potential of international unrest, economic downturn or effects of currencies, tax assessments, adjustments or anticipated rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs, (m) the possibility of reduced demand, or reductions in the rate of growth in demand, for products and services, (n) the possibility that anticipated growth, cost savings, new product acceptance, performance or approvals, or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with STERIS and Synergy's businesses, industry or initiatives including, without limitation, the consent decree or those matters described in STERIS's Form 10-K for the year ended March 31, 2014 and other securities filings, may adversely impact Company performance, results, prospects or value, (o) the possibility that anticipated financial results or benefits of recent acquisitions, or of STERIS's restructuring efforts will not be realized or will be other than anticipated, (p) the effects of the contractions in credit availability, as well as the ability of STERIS and Synergy's customers and suppliers to adequately access the credit markets when needed, and (q) those risks described in STERIS's Annual Report on Form 10-K for the year ended March 31, 2014, and other securities filings.

Important Additional Information Regarding the Transaction Will Be Filed With The SEC It is expected that the shares of New STERIS to be issued by New STERIS to Synergy Shareholders in the U.K. law scheme of arrangement transaction that forms a part of the transaction will be issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 3(a)(10) thereof.

In connection with the issuance of New STERIS shares to STERIS shareholders pursuant to the merger that forms a part of the transaction, New STERIS will file with the SEC a registration statement on Form S-4 that will contain a prospectus of New STERIS as well as a proxy statement of STERIS relating to the merger that forms a part of the transaction, which we refer to together as the Form S-4/Proxy Statement.

INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE FORM S-4/PROXY STATEMENT, AND OTHER DOCUMENTS FILED WITH THE SEC IN CONNECTION WITH THE TRANSACTION CAREFULLY AND IN THEIR ENTIRETY, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE TRANSACTION, THE PARTIES TO THE TRANSACTION AND THE RISKS ASSOCIATED WITH THE TRANSACTION. Those documents, if and when filed, as well as STERIS'S and New STERIS's other public filings with the SEC may be obtained without charge at the SEC's website at www.sec.gov, at STERIS's website at www.steris-ir.com (http://www.steris-ir.com). Security holders and other interested parties will also be able to obtain, without charge, a copy of the Form S-4/Proxy Statement and other relevant documents (when available) by directing a request by mail or telephone Julie_Winter@steris.com or (440) 392-7245. Security holders may also read and copy any reports, statements and other information filed with the SEC at the SEC public reference room at 100 F Street N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at (800) 732-0330 or visit the SEC's website for further information on its public reference room.

STERIS, its directors and certain of its executive officers may be considered participants in the solicitation of proxies in connection with the transactions contemplated by the Proxy Statement. Information about the directors and executive officers of STERIS is set forth in its Annual Report on Form 10-K for the year ended 31 March, 2014, which was filed with the SEC on 29 May, 2014, and its proxy statement for its 2014 annual meeting of shareholders, which was filed with the SEC on 9 June, 2014. Other information regarding potential participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Form S-4/Proxy Statement when it is filed.

Synergy and New STERIS are each organised under the laws of England. Some of the officers and directors of Synergy and New STERIS are residents of countries other than the United States. As a result, it may not be possible to sue Synergy, New STERIS or such persons in a non-US court for violations of US securities laws. It may be difficult to compel Synergy, New STERIS and their respective affiliates to subject themselves to the jurisdiction and judgment of a US court or for investors to enforce against them the judgments of US courts.

Participants in the Solicitation

STERIS, its directors and certain of its executive officers may be considered participants in the solicitation of proxies in connection with the transactions contemplated by the Proxy Statement. Information about the directors and executive officers of STERIS is set forth in its Annual Report on Form 10-K for the year ended 31 March, 2014, which was filed with the SEC on 29 May, 2014, and its proxy statement for its 2014 annual meeting of shareholders, which was filed with the SEC on 9 June, 2014. Other information regarding potential participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Proxy Statement/Prospectus when it is filed.

Responsibility

The directors of STERIS accept responsibility for the information contained in this document and, to the best of their knowledge and belief (having taken all reasonable care to ensure that such is the case), the information contained in this document is in accordance with the facts and it does not omit anything likely to affect the import of such information.

STERIS Synergy 2.7 Filing (http://hugin.info/149217/R/1862417/653425.pdf)
HUG#1862417

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Challenges Merger of Companies That Provide Sterilization Services to Manufacturers

Merger of Steris Corporation and Synergy Health plc Would Harm Competition for Contract Radiation Sterilization Services

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FOR RELEASE

May 29, 2015

TAGS: Bureau of Competition | Competition

The Federal Trade Commission today issued an administrative complaint charging that Steris Corporation's proposed $1.9 billion acquisition of Synergy Health plc would violate the antitrust laws by significantly reducing future competition in regional markets for sterilization of products using radiation, particularly gamma or x-ray radiation.

The Commission also authorized agency staff to seek a temporary restraining order and preliminary injunction in federal court to maintain the status quo pending an administrative trial on the merits.

According to the FTC's complaint, Steris, headquartered in Mentor, Ohio, and United Kingdom-based Synergy both provide contract sterilization services for companies that need to ensure their products are free of unwanted microorganisms before they reach customers. Implanted medical devices and human tissue products, for example, must meet stringent requirements for sterilization. For most companies, in-house sterilization is not a viable alternative. Instead, these customers bring their products to sterilization service facilities on a contract basis, typically within 500 miles of the companies' manufacturing or distribution facilities to minimize shipping costs.

Today, gamma radiation, generated by the radioactive isotope Cobalt 60, is considered the only feasible method of sterilizing large volumes of dense and heterogeneously packaged products. Only Steris and one other company, Sterigenics, provide contract gamma sterilization services in the United States, according to the complaint. At the time the proposed merger was announced, Synergy was implementing a strategy to open new plants that would provide contract x-ray sterilization services. These services – which currently are not available in the United States – would provide a competitive alternative to gamma radiation, according to the complaint. Because it uses electricity rather than Cobalt 60, x-ray does not raise many of the environmental and regulatory issues associated with gamma sterilization. According to the FTC, it is unlikely that new competitors in the market for contract radiation sterilization services would replicate the competition that would be eliminated by the merger. The Commission alleges that the challenged acquisition would eliminate likely future competition between Steris's gamma sterilization facilities and Synergy's planned x-ray sterilization facilities in the United States, thus depriving customers of an alternative sterilization service and additional competition.

The Commission vote to issue the administrative complaint and to authorize staff to seek a temporary restraining order and preliminary injunction in federal district court was 5-0. The administrative trial is scheduled to begin on October 28, 2015.

NOTE: The Commission issues an administrative complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The issuance of the administrative complaint marks the beginning of a proceeding in which the allegations will be tried in a formal hearing before an administrative law judge.

The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust{at}ftc{dot}gov, or write to the Office of Policy and Coordination, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave., NW, Room CC-5422, Washington, DC 20580. To learn more about the Bureau of Competition, read Competition Counts. Like the FTC on Facebook, follow us on Twitter, and subscribe to press releases for the latest FTC news and resources.

PRESS RELEASE REFERENCE:
FTC Dismisses Complaint against Steris and Synergy

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ftc.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION

FEDERAL TRADE COMMISSION	)	
	)	
Plaintiff,	)	
v.	)	No. ____-cv-_____
	)	
STERIS CORPORATION	)	**FILED UNDER SEAL**
	)	
and	)	
	)	
SYNERGY HEALTH PLC	)	
	)	
Defendants.	)	

PLAINTIFF FEDERAL TRADE COMMISSION'S COMPLAINT FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiff, the Federal Trade Commission ("FTC" of "Commission"), by its designated attorneys, respectfully petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC ACT"), 15 U.S.C. § 53(b), for a temporary restraining order and preliminary injunction enjoining STERIS Corporation ("Steris") from acquiring Synergy Health plc ("Synergy"). Steris proposes to acquire Synergy pursuant to an Agreement and Plan of Merger dated October 13, 2014 (the "Merger"). Absent provisional relief, Steris and Synergy (collectively, "Defendants") would be free to consummate the Merger after 11:59 p.m. on June 1, 2015. Plaintiffs require the aid of this Court to maintain the *status quo* during the pendency of

an administrative proceeding on the merits scheduled to begin on October 28, 2015, which the Commission already has initiated pursuant to Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21, and Section 5 of the FTC Act, 15 U.S.C. § 45. The administrative proceeding will determine the legality of the Merger, subject to judicial review by a federal Court of Appeals, and will provide all parties full opportunity to conduct discovery and present testimony and other evidence regarding the likely competitive effects of the Merger.

I.

NATURE OF THE CASE

1. Defendants are the second- and third-largest sterilization companies in the world, while Sterigenics International, Inc. ("Sterigenics") is the largest. Sterilization is a critical final step in the manufacture of many healthcare products, as it is necessary to eliminate bacteria and other microorganisms living on or within products and is required by the U.S. Food and Drug Administration ("FDA").

2. Steris is the largest provider of gamma radiation sterilization services in the United States with fourteen facilities, as well as ten ethylene oxide ("EO") gas sterilization facilities. Sterigenics also operates fourteen gamma sterilization facilities in the United States, along with ten EO facilities, and one electron-beam ("e-beam") radiation facility. Sterigenics also operates gamma, e-beam, and EO facilities outside the United States. Synergy operates more than three dozen contract sterilization facilities, including numerous gamma sterilization facilities outside of the United States, and currently offers only e-beam and EO sterilization services in the United States. Absent the proposed Merger, Synergy planned to [redacted]

[redacted] and [redacted] If consummated, the Merger would allow Steris to insulate itself against this competitive threat, which would have targeted Steris and Sterigenics' customers, especially its core gamma sterilization customers, and resulted in lower prices, improved quality, and increased choice for contract sterilization.

3. There are three primary methods of sterilization currently used in the United States: gamma radiation, e-beam radiation, and EO gas. Customers choose sterilization methods based on each product's physical characteristics and packaging, the volume of products requiring sterilization, and the capabilities of each sterilization modality. Gamma radiation sterilizes by exposure to a radioactive isotope, Cobalt 60. Gamma radiation has deep penetration capabilities and is favored by customers that need to sterilize dense products, such as implantable medical devices, and products with heterogeneity of density, such as products packaged in large quantities. E-beam, a second type of radiation sterilization, does not penetrate as deeply as gamma radiation, though it can be effective for low-density products sterilized in low volumes. EO is a non-radiation form of sterilization that exposes products to gas to kill unwanted organisms. EO is effective only if gas diffuses freely through packaging and makes contact with all product surfaces requiring sterilization.

4. X-ray radiation sterilization will be a close substitute for gamma sterilization. X-ray sterilization offers comparable, and possibly superior, depth of penetration, allowing it to compete for products that customers currently sterilize economically with gamma radiation. For many products, x-ray is the only functional alternative to gamma because

of the limitations of e-beam sterilization. According to Synergy, [redacted]

[redacted]

5. The relevant product market in which to analyze the effects of the Merger is no broader than contract radiation sterilization services. EO sterilization is not an economical and practical substitute for contract radiation sterilization services, because EO gas can leave a harmful residue on products, making it unsuitable for many healthcare customers. EO sterilization also requires the use of specialized, breathable packaging and faces significant restrictions in how densely products can be packed into boxes and how those boxes can be configured in the sterilization chamber, limiting the types and volumes of products that can effectively use EO. It typically takes longer to complete than radiation sterilization as well. Thus, EO sterilization is properly excluded from the relevant market.

6. A small number of medical device manufacturers use their own in-house sterilization facilities to sterilize a portion of their products. In-house sterilization is properly excluded from the relevant market because only the largest suppliers of medical devices and other products can cost-effectively sterilize any portion of their products in-house. Performing gamma sterilization internally makes economic sense only if a company produces or distributes a very large volume of product (generally in excess of [redacted] cubic feet of product annually) at a single facility. Very few companies produce the single-location volume required to justify the large upfront investment and ongoing costs associated with establishing and operating in-house sterilization. Industry trends show that medical device manufacturers and other customers are shifting more of their sterilization needs to contract providers, rather than using more in-house sterilization.

Even those that have in-house capabilities rely on contract sterilizers to provide some portion of their sterilization needs as well as back-up sterilization services in the event the in-house facilities temporarily shut down.

7. Today, e-beam is an uneconomical alternative for the vast majority of products that are sterilized with gamma radiation. Indeed, although e-beam has been available for thirty years, it still represents only about [redacted] of all contract radiation sterilization services sold in the United States while gamma accounts for the remaining [redacted] At current prices, the amount of product that customers would likely switch to e-beam sterilization in the face of a small, but significant and non-transitory increase in price ("SSNIP") for contract gamma sterilization services would be small. However, some customers are concerned about the availability and pricing of gamma sterilization in the future due to questions about the supply of Cobalt 60. As a result, e-beam may become a closer economic substitute to gamma in the future than it is today. Thus, the relevant market is no broader than contract radiation sterilization.

8. The competitive impact of the proposed merger will be most pronounced for customers that would not switch to e-beam even if gamma sterilization prices were to increase by substantially more than a SSNIP. Thus, there is also a relevant market for contract gamma and x-ray sterilization services sold to targeted customers that would not switch to e-beam in the event of a SSNIP.

9. Customers purchase gamma sterilization services from suppliers located near their manufacturing or distribution sites in order to minimize transportation costs and turnaround times. The relevant geographic markets initially affected by the proposed transaction are the areas that Synergy would have served through its planned x-ray

facilities in the [redacted] area and [redacted] which were set to open in [redacted] Synergy also planned to begin operating x-ray plants in [redacted] by [redacted] All [redacted] Synergy plants would have competed directly with nearby Steris facilities.

10. The Merger will result in substantial competitive harm in all [redacted] relevant markets, each of which is already highly concentrated under the Merger Guidelines and case law. The [redacted] million market for all contract radiation sterilization services surrounding [redacted] currently has an HHI level of over [redacted] while the other [redacted] markets—[redacted]—are also highly concentrated with HHIs ranging from at least [redacted] to more than [redacted] Analyzing the impact of the merger in the [redacted] market for contract gamma and x-ray sterilization services sold to targeted customers, which has [redacted] million in sales, yields an HHI of approximately [redacted] Similarly, each of the other [redacted] geographic areas has an even higher current concentration level in a market for contract gamma and x-ray sterilization services sold to targeted customers.

11. Synergy, although a significant competitor outside the United States, is a small U.S. contract radiation player today because it offers only e-beam sterilization services. Synergy is an actual potential entrant with its x-ray sterilization business, which would substantially augment its competitive significance. Synergy's entry with contract x-ray services would reduce concentration substantially in each relevant market and result in other procompetitive effects.

12. Synergy's U.S. x-ray strategy has been [redacted] years in the making. In 2012, Synergy's founder and CEO, Dr. Richard Steeves determined that the company should develop a

U.S. x-ray business to differentiate itself from the other major contract sterilization suppliers to enable it to become the number one global provider of contract sterilization services. Since then, Synergy has taken numerous steps to further that plan. By September 2014, Synergy's Senior Executive Board ("SEB") [redacted] the PLC Board (Synergy's Board of Directors) [redacted] the development team had secured numerous letters of interest from significant customers, and the team had transitioned from planning to implementation.

13. Synergy's proposed merger with Steris was announced on October 13, 2014. In the weeks following, Synergy [redacted] and that the New Steris would need to approve the x-ray strategy after the deal closed.

14. In January 2015, the FTC issued Second Requests to Steris and Synergy that made clear that the FTC's investigation was focused on Synergy's efforts to enter the United States with x-ray. In February, the head of Synergy's sterilization business, Andrew McLean, [redacted] While Mr. McLean claimed [redacted] customers remain interested in x-ray as an alternative to gamma, and in Synergy as an alternative to Sterigenics and Steris. In actuality, Synergy [redacted] in an effort to salvage the sale to Steris.

15. Synergy's U.S. x-ray entry would have had a large and lasting competitive impact, and a de-concentrating effect, in each relevant market. Synergy recognized that filling the facilities would take time because Synergy would be introducing a new technology to the market and because customers must validate some of their products for sterilization in the new x-ray facilities. Synergy conservatively expected its U.S. x-ray sterilization business to grow to a [redacted] share of U.S. contract gamma sterilization sales. Synergy's executives anticipated that the [redacted] Synergy assigned a [redacted] that Steris and Sterigenics would [redacted] Customers, including some of the world's largest medical device companies, share Synergy's expectation that its x-ray entry would provide them with an important alternative to contracting with Steris and Sterigenics for gamma sterilization services.

16. New entry or expansion is not likely to prevent the anticompetitive effects of the transaction—Synergy has entry advantages in x-ray that no other firm can match, including its global scale, a reputation as a quality service provider, a head-start of several years, and, as of the date of the transaction, a ten-year exclusive agreement with the [redacted] of commercially viable x-ray sterilization machines. No other firm is attempting to enter the United States with x-ray sterilization services capable of competing effectively with gamma sterilization.

17. New entry with e-beam sterilization is expensive and time consuming and would not prevent the anticompetitive effects of the Merger for targeted contract gamma and x-ray sterilization customers. Entry into gamma is extraordinarily costly, difficult, and time

consuming, and is unlikely because of the uncertain future availability and pricing of Cobalt 60, and the demanding regulatory environment.

18. Defendants cannot show that efficiencies resulting from the Merger will offset the Merger's anticompetitive effects. Most of the cost savings that Defendants claim will result are neither verifiable nor merger-specific, nor likely to be passed on to customers. According to the executive tasked with evaluating potential efficiencies, Steris's purported cost savings figures [redacted]

II.

BACKGROUND

A.

Jurisdiction and Venue

19. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and 28 U.S.C. §§1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

20. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:

Whenever the Commission has reason to believe—

> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the

> interest of the public — the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond . . .

21. Steris and Synergy are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

22. Steris is incorporated in and transacts substantial business in the Northern District of Ohio and is subject to personal jurisdiction therein. Synergy transacts substantial business in the Northern District of Ohio and is subject to personal jurisdiction therein. Venue, therefore, is proper in this district under 28 U.S.C. § 1391 (b) and (c) and 15 U.S.C. § 53(b).

B.

Defendants

23. Defendant Steris is a publicly traded corporation organized under the laws of Ohio with headquarters in Mentor, Ohio. Steris provides contract sterilization services in the United States and infection prevention and surgical products and services in more than sixty countries around the world. Steris had total revenues of over $1.6 billion in 2014, of which [redacted] derived from contract gamma sterilization services performed at facilities in Ohio, California, Illinois, Massachusetts, New Jersey, New York, Puerto Rico, South Carolina, Texas, and Utah.

24. Defendant Synergy is a publicly traded company registered in the United Kingdom, with its headquarters in Swindon, Wiltshire, United Kingdom. Synergy provides contract sterilization services in more than a dozen countries, as well as sterilization services for reusable surgical instruments and linen servicing for hospitals. Synergy had global revenues of approximately $590 million in 2014. Outside of the United States, Synergy's AST business offers contract gamma, x-ray, e-beam, and EO sterilization services. In the United States, Synergy Health U.S. Holdings Inc. is headquartered in Tampa, Florida. Synergy currently offers U.S. e-beam sterilization services at facilities in Ohio, California, Colorado, and Pennsylvania and EO sterilization in Florida, which earned [redacted] and [redacted] respectively, in 2014.

C.

The Merger and the Commission's Response

25. On October 13, 2014, Steris and Synergy signed an Agreement and Plan of Merger ("Merger Agreement"), pursuant to which Steris would acquire all shares of Synergy in a transaction valued at $1.9 billion.

26. Defendants submitted premerger notification forms to the FTC pursuant to the Hart-Scott-Rodino Act on November 7, 2014, and refiled on December 10, 2014. The Commission issued Requests for Additional Information ("Second Requests") to the parties on January 9, 2015. The purpose of the Second Requests and the Commission's investigation was to allow the Commission to assess whether it has "reason to believe" that the Merger may violate the antitrust laws. Defendants requested, received, and availed themselves of modifications to the Second Requests by agreeing that the

Commission's investigation is not discovery (or the functional equivalent thereof) for the purposes of any administrative or federal court proceeding relating to the Merger.

27. On April 15 2015, Defendants certified substantial compliance with their Second Requests, triggering a thirty-day statutory waiting period before they could consummate the Merger. Defendants subsequently agreed not to close the Merger before June 2, 2015.

28. On May 28, 2015, by a unanimous vote, the Commission found reason to believe that Defendants' have executed a Merger Agreement in violation of Section 5 of the FTC Act, and that the Merger, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. A plenary administrative trial on the merits of the merger will begin on October 28, 2015. After an initial decision by an Administrative Law Judge, the Commission will determine the legality of the Merger under Section 7 of the Clayton Act and Section 5 of the FTC Act, and an appropriate remedy if it finds liability. Under Section 11(c) of the Clayton Act, 15 U.S.C. §21(c), Defendants may appeal an adverse Commission decision directly to any U.S. Court of Appeals within whose jurisdiction Defendants reside or conduct business.

29. Also on May 28, 2015, the Commission authorized staff to commence this federal court proceeding under Section 13(b) of the FTC Act. This action seeks to enjoin Defendants from consummating the Merger pending resolution of the Commission's proceeding, and any appeals, in order to minimize interim harm to competition and preserve the Commission's ability to grant an adequate remedy if it concludes that the Merger is unlawful. Absent an order from this Court, Defendants will be free to close their transaction after 11:59 p.m. on June 1, 2015.

III.

THE RELEVANT PRODUCT MARKETS

30. The relevant product market in which to analyze the effects of the Merger is no broader than the market for contract radiation sterilization services. The effects of the Merger can also be analyzed properly in a narrower market for the sale of contract gamma and x-ray sterilization services to targeted customers that cannot economically or functionally switch to e-beam sterilization. Defining the relevant product market broadly or narrowly does not change the fact that Steris, Synergy, and Sterigenics are the only significant market participants or that substantial anticompetitive effects will result from the Merger.

A.

Background on Contract Radiation Sterilization Services

31. Contract radiation sterilization services include gamma, x-ray, and e-beam sterilization services provided by third parties.

Contract Gamma Sterilization Services

32. Gamma sterilization involves exposing products to Cobalt 60, a highly radioactive isotope, to kill microorganisms located on or within products and packaging. As Cobalt 60 decays, it emits energy in the form of photons, which do not have mass or an electric charge, allowing them to penetrate deeply into dense material.

33. Gamma sterilization is ideal for large volumes of dense products, such as large totes of medical devices, because it can penetrate several feet deep into containers. Gamma irradiators run continuously because Cobalt 60 emits radiation constantly and cannot be turned off. To prepare products for gamma sterilization, contract sterilizers transfer them

to irradiation containers, called totes, and place the containers near the Cobalt 60 source, exposing the products to gamma radiation for a set amount of time. The totes range in size from forty to seventy cubic feet, which is significantly larger than the containers used in the e-beam sterilization process. Typically, a batch of products sterilized using gamma radiation has a total turnaround time of about three to four days, including the time required to receive a shipment, irradiate it, and send it back to a customer's facility.

34. In the United States, there are a large number of products that can only be sterilized cost-effectively using contract gamma sterilization services. Steris's website includes a guide for their customers of products "where Gamma Irradiation is the Method of Choice." These include labware products; soft tissues that are recovered from donor cadavers, processed in boxes, and shipped on dry ice; liquids; filled media plates; products with a high moisture content; wet dressings that are temperature sensitive or hermetically packaged; prep pads; serums; devices or device components that are designed with occluded areas; filled syringes; and certain biological products. Other products that gamma sterilization is best suited for include products contained in impermeable packaging, orthopedic implants, surgical stents, single-use medical supplies, and many products sterilized efficiently in large batches. Gamma sterilization is particularly well-suited for these products, as well as other products of dense or varied and complex construction, because gamma radiation passes more easily through these materials than e-beam particles.

Contract X-ray Sterilization Services

35. X-ray sterilization uses a very high-powered electron beam machine to produce x-ray radiation. Historically, x-ray sterilization has not been used in the United States, in large

part because no machine existed that was capable of sterilizing products as cost effectively as gamma or other sterilization methods. Recently, however, IBA has developed equipment that can perform x-ray sterilization at a cost comparable to, and possibly lower than, gamma sterilization. IBA's accelerators have made x-ray sterilization a commercially viable alternative for products that are currently sterilized with gamma radiation.

36. X-ray sterilization combines the best features of e-beam and gamma sterilization. It offers the depth of penetration of gamma radiation, which makes it suitable for sterilizing dense products and packaging, and the quick turnaround times of e-beam sterilization. X-ray sterilization may provide significant advantages over gamma sterilization. It requires shorter processing times than gamma sterilization, providing potential inventory management advantages. It can also process multiple products with different dose requirements in the same irradiation cycle, making it more efficient than gamma sterilization. X-ray sterilization is also well-suited for processing large batches of products, and, because it uses electricity rather than Cobalt 60, x-ray does not raise many of the environmental and regulatory issues of gamma sterilization. Synergy expects that x-ray will offer quicker turnaround times, less oxidation and discoloration on plastic products, and less temperature-based damage than gamma.

Contract E-beam Sterilization Services

37. E-beam sterilization uses electrically powered accelerators to produce high-energy electron beams to kill unwanted microorganisms. The unique characteristics of the e-beam irradiation process often make it the most effective method for sterilizing small volumes of low-density, homogeneous products. E-beam machines are more efficient

than using Cobalt 60 because they can be turned on and off as needed, which ensures that they produce radiation only when they are in use. Small batches of products can often be sterilized more quickly with e-beam irradiation than gamma irradiation; an e-beam machine can sterilize some products in only a few minutes.

38. The primary drawback of e-beam sterilization is that the radiation produced does not penetrate nearly as deeply as gamma radiation, and products sterilized with e-beam radiation must be placed into smaller containers than those used in gamma sterilization. These containers are about twice the size of a copy paper box and can only hold approximately two cubic feet of product, so products delivered from customers must be loaded into small totes and exposed to e-beam radiation one box at a time. For products that are packed in dry ice, such as human tissue, the products must be unpacked from their boxes before being sterilized with e-beam. For large volumes of products, the e-beam loading process requires considerably more handling than gamma sterilization, and e-beam sterilization is not a cost-effective option for denser products. Indeed, according to customers, for many dense products, such as liquids and orthopedic implants, sterilization with e-beam technology is simply "impossible" and "[not] a viable option." Because of the significant differences between the two methods of radiation sterilization, e-beam sterilization is not a cost-effective or practical substitute for most products that currently use gamma sterilization services.

B.

The Market for Contract Radiation Sterilization Services

39. Today, gamma sterilization accounts for [redacted] of radiation sterilization services sold in the United States, and e-beam the remaining [redacted] The majority of products currently

sterilized in the United States using contract gamma sterilization services currently cannot be sterilized practically using any other method of sterilization. Contract x-ray sterilization services would compete directly with contract gamma sterilization services, and may compete with e-beam to some extent. Therefore, it is appropriate to include x-ray in the relevant market for contract radiation sterilization services.

40. Customers currently do not view e-beam sterilization as a functional or economical substitute for gamma (or x-ray) sterilization for the majority of products. Nor do Steris or Sterigenics [redacted] For this reason, there is little switching between the two sterilization methods.

41. [redacted] However, Synergy estimates that only [redacted] of current gamma sterilization volume could theoretically switch to e-beam sterilization. Neither of these estimates shows how much volume actually would switch in the face of a SSNIP. In fact, because of the limitations of e-beam, a SSNIP today would not induce customers to switch a significant volume of products from gamma sterilization to e-beam sterilization.

42. In the future, it is possible that, if contract gamma sterilization is more expensive or capacity constrained due to Cobalt 60 supply issues, there could be some switching to e-beam sterilization. Because of the possibility that contract e-beam sterilization services may become a competitive option for more contract gamma customers in the future, it may be appropriate to include contract e-beam services in the relevant product market.

43. Both x-ray and gamma sterilization services are suitable for the same high-density, heterogeneous products. X-ray sterilization services will likely be able to sterilize a number of products as well as, or better than, the gamma sterilization services these products rely on today, including: orthopedic implants, liquids, other dense products, impermeable packaging, and boxes of products that have varying densities. According to Synergy personnel, [redacted] Thus, Synergy's x-ray strategy was to take market share from gamma sterilization. Current gamma sterilization customers confirm that x-ray is a substitute for gamma.

EO Sterilization Is Not a Substitute for Radiation Sterilization Services

44. EO sterilization is properly excluded from the relevant product market. The technical differences between EO sterilization and gamma sterilization are substantial, and very few products can be cost effectively sterilized using both methods of sterilization. Accordingly, customers would not switch from radiation sterilization to EO in the face of a SSNIP for contract radiation sterilization services. [redacted]

45. Unlike radiation sterilization methods, EO sterilizes products by exposing them to a toxic gas that kills unwanted organisms. EO is a carcinogenic gas that is poisonous to humans. The EO sterilization process involves a number of steps, including placing the product in a chamber, filling the chamber with EO gas, degassing the chamber after sterilization, and aerating the product to remove or reduce EO residue on the product. EO sterilization requires that the design of products and packaging allow EO gas to move freely over material requiring sterilization. Thus, products must be packaged in permeable material and loaded in a configuration that allows the EO gas to reach all surfaces. The volume, density, and overall configuration of the load can limit gas exposure and removal after processing. The EO sterilization process also exposes products and packaging to a range of pressures at an elevated temperature, so products must be designed to withstand this environment. Even when EO could theoretically be used to sterilize some products, the process often takes significantly longer than other sterilization methods because products that have been exposed to EO must be quarantined for a period of days until all the gas has dissipated and no or acceptable levels of residue remain on the product.

In-House Sterilization Is Not a Viable Substitute for Most Customers

46. In-house gamma sterilization services are properly excluded from the relevant product market. Most customers cannot use in-house gamma sterilization to meet any of their needs cost effectively, and customers do not rely on in-house gamma sterilization facilities to satisfy all of their requirements. A minimum of approximately [redacted] cubic feet of gamma-sterilized product annually at a single production or distribution facility is required to justify moving sterilization for a given facility in-house. Generally, only large medical device manufacturers produce sufficient volumes at a single location

to justify the large upfront investment and ongoing expenses of opening and operating an in-house gamma facility. Small customers are not capable of bringing gamma sterilization in-house economically, and no in-house sterilizer in the continental United States sells excess capacity to its competitors. Thus, only approximately 20% of gamma sterilization is performed in-house. Further, industry trends show that medical device manufacturers and other customers are shifting more of their sterilization needs to contract providers, rather than using more in-house sterilization.

47. There are substantial regulatory and practical barriers to establishing a gamma facility in the United States. Moreover, it is likely to become more difficult to justify establishing in-house gamma sterilization capabilities in the future because there are questions about the future availability and supply of Cobalt 60. Those concerns have become more acute since Sterigenics, through its acquisition of Nordion, Inc. ("Nordion") in 2014, became the sole supplier of Cobalt 60. [redacted]

48. Customers would not increase the volume of products sterilized with in-house gamma sterilization by an amount sufficient to make a SSNIP for all contract gamma sterilization services unprofitable. Even large customers that have in-house sterilization capabilities require contract gamma sterilization services as backup when their facilities are down, as well as contract services in areas where they do not produce enough product to justify an in-house facility. Further, even if some customers would switch some of their volume to in-house facilities in response to a SSNIP, a hypothetical monopolist could still profitably

increase prices by price discriminating against the majority of customers who cannot economically switch to in-house.

C.

The Market for Contract Gamma and X-ray Sterilization Services Sold to Targeted Customers

49. The anticompetitive effects of the Merger will be most significant in the market for contract gamma and x-ray sterilization services sold to customers that cannot economically or functionally switch affected products to e-beam sterilization. As Steris noted in a presentation to the FTC, [redacted]

50. [redacted] Thus, contract gamma sterilization providers can target and effectively price discriminate against customers that make products that cannot economically or functionally use any method of sterilization other than gamma radiation, charging them higher prices than customers that could cost-effectively use other means of sterilization.

51. While customers could switch some portion of products currently utilizing contract gamma sterilization services to e-beam sterilization, especially if future prices for

contract gamma sterilization increase as a result of Cobalt 60 supply issues, that group is likely relatively small. For those products that cannot switch from contract gamma sterilization services—e.g., dense medical devices, products that contain liquid, and products that are sterilized efficiently in large containers—e-beam sterilization providers will not constrain the prices of contract gamma sterilization service providers. Nor will the possibility of utilizing an in-house sterilization facility constrain contract gamma sterilization prices. Only contract x-ray sterilization services would provide competition against the contract gamma services that these customers must use today. Thus, even if a SSNIP to *all* contract gamma sterilization and x-ray customers would be unprofitable because some customers would switch to e-beam sterilization, a hypothetical monopolist of contract radiation sterilization services could profitably impose a SSNIP on targeted customers that cannot switch.

IV.

THE RELEVANT GEOGRAPHIC MARKETS

52. The relevant geographic markets in which to analyze the competitive effects of the Merger are the areas within approximately [redacted] miles of each of the [redacted] locations where Synergy planned to build an x-ray sterilization plant: [redacted]

53. Contract radiation sterilization providers compete for customers generally located within approximately [redacted] miles of their plants. Contract radiation sterilization customers are located throughout the country, but most strongly prefer to purchase services in the areas

around their manufacturing and distribution sites in order to minimize transportation costs and turnaround times. Transportation costs can be a significant part of the total cost of contract sterilization, and the delay and added cost of shipping a product away from a company's supply chain and back again can create significant logistical issues and become cost prohibitive. However, some customers may be able to use sterilization providers that are beyond this radius if the provider has a facility near its regular shipping routes. Contract radiation sterilization companies therefore locate their plants near the customers for which they expect to compete and evaluate competition and set prices regionally.

54. [redacted]

55. In the first phase of its entry into the United States, Synergy planned to build [redacted] x-ray facilities: [redacted]

56. Synergy's [redacted] x-ray sterilization facility would compete directly with Steris's [redacted] facilities. Synergy identified potential customers for this facility throughout [redacted] including in [redacted] as well as in [redacted] and [redacted] Synergy planned to open its [redacted] x-ray plant in [redacted]

57. Synergy's [redacted] x-ray facility was also set to open in [redacted] This facility, which would compete with Steris's [redacted] and [redacted] planned to target key customers throughout [redacted]

58. In the second phase of its rollout, Synergy planned to build additional x-ray sterilization facilities in [redacted] in [redacted] Synergy's [redacted] x-ray plant would compete with Steris's [redacted] facilities. Its [redacted] x-ray facility would compete with Steris's [redacted] plant. And Synergy's [redacted] facility would compete with Steris's [redacted] plants in [redacted]

59. After building all [redacted] x-ray facilities, Synergy would have a plant within [redacted] miles of the supply chain of the vast majority of U.S. sterilization customers.

V.

MARKET STRUCTURE

60. Steris and Sterigenics are currently the only providers of contract gamma sterilization services and the leading providers of radiation sterilization services. When the proposed Merger was announced, Synergy had begun implementing its strategy to bring a disruptive product to the U.S. contract sterilization market. Synergy's entry into the United States with contract x-ray sterilization services would compete directly with Steris and Sterigenics' contract gamma businesses, and would produce substantial consumer benefits that no other market participant or potential entrant could replicate.

A.

Market Participants

Contract Gamma Sterilization Services

61. Steris has twelve gamma sterilization facilities in the United States: Ontario, California; Libertyville, Illinois (three separate facilities); Northborough, Massachusetts; Wippany, New Jersey; Chester, New York; Groveport, Ohio; Vega Alta, Puerto Rico; Spartanburg, South Carolina; El Paso, Texas; and Sandy, Utah. Steris achieved [redacted] in revenues from contract sterilization services in 2014, with approximately $[redacted] coming from its U.S. contract gamma sterilization operations.

62. Sterigenics, the largest contract sterilization services provider in the world, and the only other U.S. contract gamma sterilization provider, is headquartered in Oak Brook, Illinois. It has fourteen U.S. gamma sterilization facilities located in the United States: West Memphis, Arkansas; Corona, California; Gilroy, California; Hayward, California; Tustin, California; Gurnee, Illinois; Schaumburg, Illinois; Rockaway, New Jersey; Salem, New Jersey; Charlotte, North Carolina; Haw River, North Carolina; Westerville, Ohio; Fort Worth, Texas; and Mulberry, Florida. In 2014, Sterigenics earned an estimated [redacted] from its U.S. contract gamma sterilization facilities.

Contract X-ray Sterilization Services

63. Synergy is the third major global provider of contract sterilization services, but does not offer contract gamma sterilization services in the United States. Synergy had a well-developed strategy to enter the United States with contract x-ray sterilization services that would have competed with contract gamma sterilization services. Outside of the United

States, Synergy already owns and operates a facility in Däniken, Switzerland, that performs both gamma and x-ray sterilization services.

64. Prior to the proposed Merger, Synergy expected to win a [redacted] share of U.S. contract gamma sterilization services revenue. Synergy expected that its first [redacted] x-ray facilities in the [redacted] areas would earn a combined $[redacted] [redacted]n 1[redacted] and $[redacted] million in [redacted], by which time all [redacted] of its facilities would be operational. Synergy forecasted its annual x-ray revenues to reach $[redacted] million.

65. Some small e-beam sterilization services providers, like [redacted] may attempt to provide x-ray sterilization services [redacted], but these firms will not be able to compete with gamma sterilization services because, [redacted]. Instead, they will be relegated to small-scale x-ray sterilization for a limited group of customers.

Contract E-beam Sterilization Services

66. Synergy is the leading provider of contract e-beam sterilization services in the United States with e-beam facilities located in San Diego, California; Denver, Colorado; Saxonburg, Pennsylvania; and Lima, Ohio. Synergy earned $[redacted] million from its U.S. e-beam contract sterilization services in 2014. [redacted]

67. Sterigenics operates an e-beam facility in San Diego, California, that generated approximately [redacted] in sterilization sales in 2014. Sterigenics also operates a

facility in Bridgeport, New Jersey, that is dedicated to sterilizing U.S. mail with e-beam and a low-power x-ray machine. The Bridgeport facility generated [redacted] in 2014.

68. Steris does not currently provide e-beam sterilization services in the United States, but it also is [redacted]

69. There are several smaller providers of e-beam sterilization serving the United States that operate one or two locations.

- E-BEAM Services Inc. ("E-BEAM Services"), headquartered in Cranbury, New Jersey, has two contract e-beam sterilization services facilities, one in Cranbury and the other in Lebanon, Ohio. Medical device customers are skeptical of working with E-BEAM Services for sterilization, however, citing a lack of technical expertise. Steris characterizes E-BEAM Services as being limited to industrial irradiation of wire, cable, and tubing. In 2014, E-BEAM Services earned approximately [redacted] in revenue from e-beam sterilization services.

- Nutek operates a contract sterilization facility in Hayward, California. In 2014, the company earned approximately [redacted] in revenue from contract e-beam sterilization services. [redacted] Nutek lacks the expertise and efficiency of Steris, Sterigenics, and Synergy.

- Iotron Industries Canada, Inc. ("Iotron") is a Vancouver, British Columbia, company that opened a contract e-beam sterilization facility in Columbia City, Indiana, in 2012. In 2014, the company's revenues from the Indiana facility approached [redacted] of which approximately [redacted] were attributable to medical device and other healthcare related sterilization. Iotron serves mostly non-medical customers because medical device and other companies question its technical expertise and experience with their products. Even though Steris has four gamma sterilization facilities serving the area, Steris Isomedix's Vice President of Sales and Marketing could not name a single customer that it has ever lost to Iotron.

- Avantti Medi Clear is based in Tijuana, Mexico, [redacted]

[redacted]. The company has been working for [redacted] years to establish that facility but has no sales at this time.

B.

Market Concentration

70. Each relevant market is currently highly concentrated under the Horizontal Merger Guidelines and relevant case law, and Synergy's U.S. x-ray strategy would have resulted in substantial de-concentration and procompetitive effects in each relevant market.

71. The Horizontal Merger Guidelines and courts measure concentration using the Herfindahl-Hirschman Index ("HHI"). HHI levels are calculated by totaling the squares of the market shares of each firm in the relevant market. Changes in HHI levels are the difference between pre- and post-merger HHI levels. Under the Horizontal Merger Guidelines, a relevant market is "highly concentrated" if it has an HHI level of 2,500 or more. In highly concentrated markets, the Horizontal Merger Guidelines view changes in the HHI level of 200 points or more as evidence that a merger should be presumed likely to create or enhance market power, unless Defendants rebut this presumption by submitting persuasive evidence showing the merger is unlikely to enhance market power.

72. In the approximately $[redacted] million Midwest market for contract radiation sterilization services, the current HHI is over [redacted] The [redacted] other relevant markets where Synergy plans to establish x-ray sterilization facilities, [redacted] are also highly concentrated, with HHIs of more than [redacted] respectively.

73. Each relevant market for contract gamma and x-ray sterilization services sold to targeted customers is also highly concentrated. There are only two suppliers of contract gamma sterilization services today, and absent the Merger, Synergy's x-ray sterilization would

provide a third alternative. The high market concentration for these targeted customers is evidenced by the high concentration for contract gamma sterilization services: in the $[redacted] million contract gamma sterilization business in the [redacted] area, the current HHI level is approximately [redacted]. In the other [redacted] areas where Synergy plans to enter, concentration levels are even higher, ranging from more than [redacted] to at least [redacted] The market shares and concentration levels in gamma markets are a good proxy for the market shares and concentration in gamma/x-ray markets for targeted customers.

VI.

ANTICOMPETITIVE EFFECTS

74. The anticompetitive effects of the Merger arise from the elimination of the likely future competition from Synergy's deployment of x-ray sterilization in the United States. Steris and Sterigenics are two of the three significant contract radiation sterilization providers and the only two contract gamma providers in the United States in each of the geographic markets at issue. Synergy, as the only major worldwide sterilization company without a gamma offering in the United States, was on the verge of entering with what it considered to be a disruptive sterilization technology, x-ray, that would allow it to compete directly for Steris and Sterigenics' customers.

75. By October 2014, just days before the announcement of the Merger, Synergy determined that it would have [redacted] operating by [redacted] Synergy envisioned building a total of [redacted] sites and achieving broad mainstream adoption of x-ray sterilization technology by [redacted]

76. Synergy also considered the competitive impact its entry would have on U.S. gamma sterilization competitors, and concluded that Steris and Sterigenics would [redacted] With the proposed acquisition, there will be no [redacted] nor will this promising sterilization technology be available to U.S. sterilization customers.

A.

Synergy Was Entering the Relevant Markets Prior to the Merger

The Early Stages of Synergy's U.S. X-ray Plan

77. In 2012, months after Synergy's acquisition of the x-ray facility in Däniken, Switzerland, the company's founder and CEO, Dr. Richard Steeves, proposed a plan to launch x-ray sterilization in the United States to [redacted] This plan, Dr. Steeves explained in an April 2013 Synergy leadership conference, was [redacted]

[redacted]

78. In May 2013, Dr. Steeves told Synergy's board of directors (the "PLC Board") that the x-ray launch in the United States had become a [redacted] The following month, [redacted] Before Mr. McLean had even started his job, Dr. Steeves told him that he was [redacted] and that

[redacted] Mr. McLean worked on the x-ray project from his first day on the job.

The X-ray Plan Ramp-Up

79. In 2014, the Synergy x-ray team took the project from the conceptual stage to the planning and implementation phase.

80. The team worked with [redacted] to configure equipment to be used and, on September 15, 2014, reached an agreement with [redacted] for the exclusive right to [redacted] x-ray technology in the United States. [redacted]

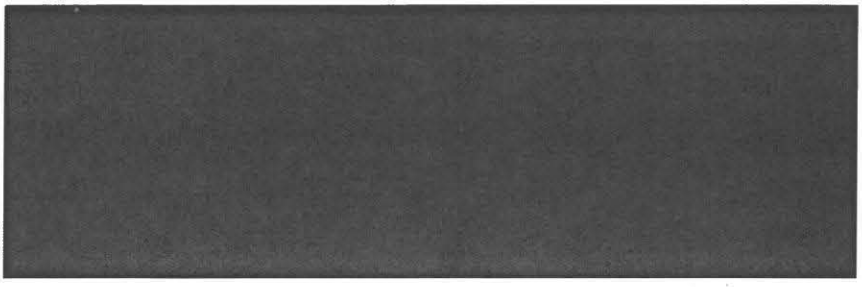
81. The x-ray team also worked to cultivate customer interest to support the business case and procured letters of interest ("LOIs") from many customers in August and September 2014. Key customers like [redacted] and [redacted] all submitted LOIs, as did [redacted] and [redacted]

82. The team prepared a business case for the [redacted] facilities based on a detailed analysis of the U.S. regional markets. On September 17, 2014, Synergy's SEB [redacted] There are seven members of the SEB: Synergy's CEO (Dr. Steeves); Synergy's COO (Adrian Coward); Synergy's Group Finance Director (Gavin Hill); Synergy's Group Company Secretary; CEO of the AST business (Mr. McLean); an executive from Synergy's healthcare services division; and a human resources executive. [redacted] The details of the strategy presented to the SEB [redacted] This presentation:

- Sought [redacted] and [redacted]
- Identified the [redacted] to be opened in [redacted] and [redacted]
- Explained that Synergy [redacted]
- Stated that [redacted] would be to [redacted] and [redacted]
- Described [redacted] to be to [redacted] and [redacted]

83. The same day, Mr. McLean emailed the x-ray team that the SEB had [redacted]

[redacted]



84. The day after the SEB meeting, September 18, 2014, Synergy's PLC Board met and discussed the U.S. x-ray strategy. Dr. Steeves, Mr. Coward, and Mr. Hill, all members of the SEB, are three of the seven members of the PLC Board; three of the four remaining members are outside directors, and one is the Non-Executive Chairman of the PLC Board. Mr. Coward explained that [redacted] He requested that the PLC Board [redacted] Dr. Steeves also explained to his fellow PLC Board members that, with [redacted] The PLC Board approved [redacted]

85. After the September SEB and PLC Board meetings, the U.S. x-ray project was renamed [redacted] and implementation of the x-ray plan began. Synergy expanded the size of the team to [redacted] employees, including personnel from operations, engineering, accounting, and maintenance to assist through construction and start-up of operations. On October 7, 2014, Mr. McLean brought the team together for a [redacted] The slide presentation that opened the meeting stated that:

- [redacted]
- [redacted]

The slides also cautioned that, [redacted]

86. The Merger of Synergy and Steris was announced less than a week later, on October 13, 2014.

Synergy's Actions Post-Merger Announcement

87. In the weeks following the announcement of the deal, Synergy recognized that [redacted] As Mr. Tyranski wrote a week after he learned of the transaction, [redacted] The Synergy x-ray team also recognized that [redacted] Thus, Synergy [redacted] but acknowledging that the [redacted]

88. The PLC Board, in its November 2014 meeting, [redacted] because, [redacted]

89. Synergy's management continued to believe that [redacted]

[redacted] Synergy's senior management expected to [redacted] while acknowledging that they would [redacted]

90. [redacted] The [redacted] team leader created a detailed timeline describing each step needed to begin operations at the [redacted] x-ray facility by [redacted] the [redacted] The agreement with [redacted] reached on [redacted] was memorialized in writing and executed on [redacted] giving Synergy [redacted] The [redacted] was pushed back from [redacted] to [redacted] to accommodate the anticipated closing of the Steris transaction.

91. The x-ray strategy continued to have the open support of Synergy leadership. The plan to enter the United States with [redacted] facilities, followed on by [redacted] additional facilities, was incorporated into the FY 2016 Strategic Plan for the AST business. In a November 4, 2014, statement to investors attached to a security filing, Synergy reported:

> We are pleased to announce that we have signed an agreement with IBA for X-ray technology to be deployed in the United States, supplemented by our in-house knowledge and expertise. Our X-ray services are now the fastest growing of our AST technologies, driven by the higher levels of quality, favourable economics and faster processing speed, which helps our customers to reduce their working inventories. Most recently the first FDA approval of a Class III medical device was achieved by one of our major global customer partners, paving the way for further conversions.

Synergy's Actions After the FTC Issued Second Requests

92. On January 9, 2015, the FTC issued Second Requests to Defendants specifically requesting documents and information relating to potential competition between their x-ray and gamma sterilization businesses.

93. At a February 19, 2015, meeting with FTC staff, Mr. McLean announced that [redacted]

94. On February 24, 2015, Mr. McLean executed a declaration to evidence this [redacted] using an [redacted] as a pretext for doing so. As support for that [redacted] Mr. McLean attached copies of e-mails he personally received just days before. That evening, Mr. Tyranski wrote the x-ray team leaders: [redacted] Mr. Tyranski planned to [redacted] The next day, they informed [redacted] that Synergy would be [redacted] Peter Grief, a Project Endurance team member, recognized that it was [redacted] but he was [redacted]

B.

Synergy's U.S. X-ray Entry Would Result in Substantial Procompetitive Effects

Synergy's Entry Would Have a Significant De-concentrating Effect on the Relevant Markets

95. Synergy expected its x-ray entry would have a large and lasting competitive impact. Synergy expected to win a [redacted] share of all of the contract gamma sterilization business of Steris and Sterigenics in the United States.

96. Synergy projected approximately $[redacted] million in sales for its [redacted] x-ray facility in [redacted] increasing to approximately $[redacted] million annually by [redacted] Synergy planned to target [redacted] among others, all of whom have expressed interest in converting product to x-ray and who are currently Steris and/or Sterigenics customers.

97. To provide a sense of the magnitude of the de-concentrating effect that Synergy's x-ray entry would have produced, it is informative to calculate future nationwide HHI levels with and without the Merger based on Synergy's ordinary course documents, even though the markets here are local. Synergy's x-ray entry, at a minimum, would reduce the HHI for U.S. contract radiation sterilization by more than [redacted] points. For contract gamma sterilization, Synergy's x-ray entry would, at a minimum, reduce the HHI by approximately [redacted] points.

98. To provide a sense of the magnitude of the de-concentrating effect that Synergy's x-ray entry would have produced on a local level, it is informative to calculate future HHI levels for the [redacted] facility, which would have opened in [redacted] Based on Synergy's revenue projections, in [redacted] the HHI would have decreased, at a minimum, by more than [redacted] points in the market for contract radiation services and by at least [redacted] points in the contract gamma/x-ray market.

99. [redacted] documents confirm that Synergy's [redacted]

- [redacted]
- [redacted]

Synergy's X-ray Entry Would Have Created Substantial Price and Non-Price Benefits for Customers

100. Synergy expected to enter the highly concentrated relevant markets and win the business of the incumbents' highest value customers. Synergy knew that, in response to its entry, Steris and Sterigenics would vigorously defend their businesses and fight to keep their core gamma customers by, among other things, lowering prices.

101. Synergy designed its x-ray strategy to [redacted] In response to its entry, Synergy expected Steris and Sterigenics to [redacted] In the face of this competitor response, which Synergy described as [redacted] Synergy planned to set its x-ray rates at a level that [redacted]. Synergy also planned to exploit [redacted]

102. Synergy officials called the U.S. x-ray strategy [redacted] and anticipated a [redacted] Even after Defendants announced the Merger, Synergy executives continued to tout x-ray's competitive potential. In a November 2014 email, Synergy's CEO told Steris's CEO that [redacted]

103. Mr. Tyranski, Synergy's AST President, testified that the [redacted] for Synergy's U.S. x-ray strategy was [redacted] which Synergy planned to [redacted] He acknowledged that [redacted] would be the [redacted] Similarly, Synergy's AST

Business Analyst testified that [redacted]

He explained that Synergy [redacted] because [redacted]

104. Dr. Steeves testified that Synergy [redacted]

[redacted]

Dr. Steeves concluded that [redacted] given Synergy's goal of [redacted]

105. Customers, including some of the [redacted], share Synergy's expectation that its x-ray entry would provide them with an alternative to contracting with Steris and Sterigenics for gamma sterilization services. Customers believe that Synergy's x-ray services would compete directly with Steris and Sterigenics' gamma sterilization offerings and could be a potentially superior alternative to gamma sterilization. Moreover, many customers state that they would consider validating new

products for x-ray sterilization and switching a portion of their products that are currently sterilized with contract gamma radiation to Synergy's x-ray sterilization when it becomes available.

106. Some customers are concerned that, because Sterigenics controls the limited supply of Cobalt 60, their gamma sterilization prices may rise significantly in the future. Thus, these customers are interested in moving their business to x-ray sterilization if Synergy enters, to protect themselves from these anticipated gamma sterilization price increases.

107. Customers anticipate that their purchases of x-ray sterilization services will grow incrementally. Synergy understood that [redacted] and therefore expected [redacted] Despite the time and costs required to switch to x-ray, many customers state that they are willing to switch current and/or future products due to the benefits of contract x-ray sterilization. In fact, even though Synergy has not yet opened a facility in the United States, J&J already invested $[redacted] to validate its Class III medical device, Surgicel, with Synergy's x-ray sterilization services. The FDA approved x-ray sterilization for Surgicel in September 2014.

108. Other companies, including [redacted], have also tested sample products at Däniken to determine the feasibility and effects of using x-ray sterilization on their products, and several more are interested in doing so. [redacted] and others have been in recent discussions with Synergy regarding the possibility of validating their FDA Class III products at Synergy's Däniken, Switzerland, x-ray facility.

109. Numerous significant purchasers of contract gamma sterilization services have expressed concern that, if Defendants consummate the Merger, the substantial competitive benefits

of Synergy's U.S. x-ray entry will never materialize. Customers have explained that having the credible threat of switching to an independent Synergy's x-ray sterilization services would provide them greater bargaining leverage when negotiating contract gamma sterilization prices with Steris and Sterigenics. Even more valuable to these customers is the prospect of a sterilization option that promises to be a superior technology, with better performance, greater efficiency, and possibly lower prices. Customers fear that, if the Merger closes, terminating Synergy's independent entry with x-ray sterilization services will deprive them of these substantial price and non-price benefits.

110. Customers have also expressed concern that Steris likely has significantly less incentive to bring competitive x-ray sterilization services to the United States than an independent Synergy. Moreover, even if the combined company were to proceed with some form of U.S. x-ray rollout, customers would lose the benefits of having an independent alternative to Steris's gamma sterilization services.

VII.

ENTRY WILL NOT PREVENT THE MERGER'S COMPETITIVE HARM

111. Neither new entry nor expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Merger. Entry by a new gamma or e-beam sterilization provider would not prevent the harm created by Steris acquiring Synergy and preventing Synergy's independent entry into the U.S. x-ray sterilization business. No other firm could enter the United States with x-ray sterilization services that would recreate the benefits that Synergy's entry would have provided.

A.

Barriers to Entry for X-ray Sterilization Services

Synergy Has X-ray Entry Advantages Unmatched by Any Other Firm

112. Synergy is the firm best positioned to enter the relevant markets with x-ray sterilization services. Synergy's desire to be a global supplier of contract sterilization services provides it with an incentive to enter the United States with x-ray sterilization services that no other firm in the world shares. Today, Synergy is small player in the U.S. contract radiation sterilization services business because the only radiation sterilization that it provides is e-beam, so it cannot compete for the vast majority of customers' business. X-ray is the only technology that can compete directly for all gamma sterilization customers, especially those that need to sterilize large volumes of dense products.

113. At the time Synergy executed the Merger Agreement, it had already devoted over two years to its U.S. x-ray entry strategy, and was in the implementation phase. It acquired the Däniken, Switzerland, x-ray sterilization facility in 2012, and has operated it for more than two years, developing an expertise with x-ray sterilization on a commercial scale. Synergy viewed the Däniken facility as a [redacted] For well over a year, customers had been sending products to Däniken for x-ray testing so they could validate products for sterilization at the U.S. x-ray facilities as soon as they became available.

114. At the time of the Merger Agreement, Synergy had also secured a unique technological advantage: exclusive access to IBA's x-ray machines. No other x-ray machine available today can economically achieve the power generation and throughput capabilities of

IBA's machines and compete effectively with contract gamma sterilization services. In fact, Synergy's Däniken facility manager testified that [redacted] He further estimated that it would take [redacted] to develop technology that could achieve what [redacted] machines can do today. At the time of the Merger announcement, [redacted] had agreed [redacted] Synergy viewed that [redacted]

115. No potential entrant could replicate the substantial benefits that Synergy's entry into the United States with x-ray sterilization services would have provided. No potential x-ray entrant has the ability to compete as effectively as Synergy would have. In order to enter the United States and compete as effectively as Synergy, a potential entrant would need to win the business of large medical device manufacturers that prefer to sterilize most of their products with the three major sterilization suppliers. Steris, Sterigenics and Synergy have the experience and scale and scope of operations to meet the needs of large medical device manufacturers effectively and economically. No potential entrant has the reputation or size of operations that these large customers require. Nor does any potential entrant have access to an x-ray plant like Synergy's Däniken facility, where it could test and validate products for potential customers. In addition, no company has an agreement with IBA to use its x-ray equipment, and [redacted]. Finally, any firm seeking to

enter the United States with x-ray sterilization services would be two or more years behind where Synergy was at the time it executed the Merger Agreement with Steris.

116. No firm is currently working to enter the United States with x-ray sterilization services that could compete as effectively as Synergy. [redacted] Some companies have contemplated [redacted]; however, [redacted] could not compete effectively or economically with contract gamma sterilization as Synergy planned to do with its high-power x-ray machines. [redacted], like e-beam machines, lack the penetration and throughput capabilities to sterilize large volumes of dense products. Only gamma sterilization and high-power x-ray sterilization services can sterilize these products economically and effectively.

B.

Barriers to Entry for Gamma Sterilization Services

117. Entry by establishing a gamma sterilization plant is extraordinarily difficult and time consuming, and is very unlikely to occur in a timely fashion, if ever. Despite the growth in demand for gamma sterilization services, no contract provider has built a new gamma sterilization facility in the United States in over fifteen years. The barriers to entry for a gamma sterilization facility are significant. Establishment of a commercial-scale gamma sterilization business requires a substantial sunk investment, significant technical

expertise, and regulatory authorizations that are difficult or impossible to obtain. Strict regulations govern gamma sterilization facilities because of the safety and environmental risks associated with storage of large volumes of radioactive material, and future legislative restrictions threaten to prohibit opening a new gamma facility in the United States altogether.

118. It is expensive to build and operate a gamma sterilization facility. The initial capital investment to build a single plant is between $[redacted] and $[redacted]. Further, to compete effectively for gamma sterilization business, an entrant would likely have to establish at least two facilities to be able to ensure that services are not interrupted during routine or unexpected shutdown periods.

119. Even more significant than the capital investment required are the regulatory barriers to entry. Cobalt 60 is an unsafe material that poses considerable environmental and health risks, so its procurement, handling, and storage are heavily regulated. The Nuclear Regulatory Commission and the International Atomic Energy Agency regulate the design of gamma sterilization facilities and the shipping of Cobalt 60. The Environmental Protection Agency and state agencies also regulate environmental safety aspects of handling and storing Cobalt 60 at gamma sterilization facilities. Because of this strict regulatory regime, building and licensing a gamma sterilization facility can take years, if future plant construction will be permitted at all.

120. In addition to the high cost and challenging regulatory environment, the future of gamma sterilization in general is uncertain. According to the CEO of Synergy's AST business,

[redacted]

[redacted] The future availability of Cobalt 60 is also unpredictable, and the prices for this essential input are expected to increase. A new gamma sterilization entrant would have to secure Cobalt 60 from Sterigenics, with which it would also have to compete. The many obstacles to gamma sterilization entry contributed to Synergy's decision to pursue entry with x-ray technology, rather than gamma, to target the U.S. gamma sterilization business.

C.

Barriers to Entry for E-beam Sterilization Services

121. E-beam sterilization entry is time-consuming, expensive, difficult, and would not prevent the competitive harm from the proposed transaction. It takes at leas[redacted] years to plan and open an e-beam sterilization facility, and may take significantly longer. For example, [redacted]. After building a sterilization plant, a potential entrant would need to secure customers willing to use its facility. Most customers need to test and validate their products with a potential e-beam sterilization provider before committing to use its services. It is difficult, and sometimes impossible, to conduct such testing before an e-beam facility is operational. Opening a new e-beam sterilization facility typically costs between [redacted] million upfront, including the costs for obtaining a building, a conveyor system, an electron accelerator, and required shielding equipment. Customers, even smaller localized ones, generally require contract e-beam sterilization providers to offer backup facilities for times when an e-beam machine is unavailable, whether for maintenance or in case of mechanical failure. Thus, an entrant would likely have to build

a facility with multiple e-beam machines or multiple facilities to enter and compete effectively for any significant amount of business.

122. Even if it were possible to enter the market in a timely fashion with e-beam sterilization services, such entry would not prevent the anticompetitive harm from the Merger. The evidence shows that there is a large universe of contract gamma sterilization customers that cannot switch to e-beam, but would switch to x-ray if it were available. E-beam entry would not affect the ability of contract gamma or x-ray sterilization providers to target these customers for price increases. Moreover, there is no evidence that any small fringe e-beam sterilization firm, or a *de novo* entrant, is likely to expand or enter the market in a significant manner. As Steris explains:

[redacted]

As a result, these fringe providers have been unable to grow beyond a tiny share, collectively, of contract radiation sterilization services.

123. The only company likely to enter into the e-beam sterilization business in the future and have a significant market impact is [redacted]

VIII.

EFFICIENCIES WILL NOT COUNTERACT THE MERGER'S COMPETITIVE HARM

124. Extraordinary merger-specific efficiencies are necessary to outweigh the Merger's likely significant harm to competition in the relevant markets. Defendants cannot demonstrate cognizable efficiencies sufficient to outweigh the substantial competitive harm likely to result from the Merger.

125. The cost savings that Defendants claim will result are not verifiable, nor are they merger-specific or likely to be passed on to customers. According to the executive tasked with evaluating potential efficiencies, Steris's purported cost savings figures [redacted]

IX.

LIKELIHOOD OF SUCCESS ON THE MERITS AND NEED FOR RELIEF

126. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed merger is unlawful, to seek preliminary injunctive relief to prevent consummation of a merger until the Commission has had an opportunity to adjudicate the merger's legality in an administrative proceeding. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities, using a sliding scale. The principal equity in cases brought under Section 13(b) is the public's interest in effective enforcement of the antitrust laws. Equities affecting only Defendants' interests cannot tip the scale against a preliminary injunction.

127. The Commission is likely to succeed in proving in the administrative proceeding that the effect of the Merger may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act or Section 5 of the FTC Act. In particular, Complaint Counsel for the Commission is likely to succeed in demonstrating, among other things, that:

a. The Merger would have anticompetitive effects in the markets for contract radiation sterilization services, and narrower markets therein, in the [redacted]

b. Substantial and effective entry or expansion into these markets would not be likely, timely, or sufficient to offset the anticompetitive effects of the Merger; and

c. Any efficiencies that Defendant may assert will result from the Merger are speculative, not merger-specific, and are, in any event, insufficient as a matter of law to justify the Merger.

128. Preliminary relief is warranted and necessary. Should the Commission rule, after the administrative trial, that the Merger is unlawful, reestablishing the *status quo* would be difficult, if not impossible, if the Merger has already occurred in the absence of preliminary relief. Allowing the Merger to close before the completion of the administrative proceeding would cause irreparable harm by enabling the combined firm to begin altering Synergy's operations and business plans, accessing Synergy's sensitive business information, eliminating key Synergy personnel, and stalling Synergy's x-ray roll out efforts. In the absence of relief from this Court, substantial harm to competition would occur in the interim.

129. Accordingly, the equitable relief requested here is in the public interest.

WHEREFORE, Plaintiff respectfully requests that this Court:

a. Temporarily restrain and preliminarily enjoin Steris from acquiring Synergy, all or in part, or from taking any further steps to consummate the Merger, or otherwise effecting a combination of Defendants Steris and Synergy, consistent with Plaintiff's Proposed Order;

b. Retain jurisdiction and maintain the *status quo* until resolution of the administrative proceeding that the Commission has initiated; and

c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Dated: May 29, 2015

Respectfully submitted,

[signed filed]

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CERTIFICATE OF SERVICE

I hereby **CERTIFY** that, on the 29th day of May, 2015, I filed the foregoing Complaint for Temporary Restraining Order and Preliminary Injunction with the Clerk of the Court.

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Attorney for Plaintiff Federal Trade Commission

I hereby **CERTIFY** that, on the 29th day of May, 2015, I served the foregoing Complaint for Temporary Restraining Order and Preliminary Injunction on the following counsel for Defendants via electronic mail:

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

FEDERAL TRADE COMMISSION,	)	**CASE NO. 1:15 CV 1080**
	)	
Plaintiff,	)	**JUDGE DAN AARON POLSTER**
	)	
vs.	)	**OPINION AND ORDER**
	)	
STERIS CORPORATION, et al.,	)	
	)	
Defendants.	)	

On May 29, 2015, the Federal Trade Commission (FTC) filed a Complaint for Temporary Restraining Order and Preliminary Injunction against Defendants Steris Corporation (Steris) and Synergy Health plc (Synergy). (Doc #: 1.) The FTC asked the Court to grant immediate injunctive relief under Section 13(b) of the Clayton Act to prevent Steris from acquiring its alleged potential competitor, Synergy, on June 1, 2015. The parties agreed to maintain the status quo pending an expedited hearing on the motion for preliminary injunction and the Court's ruling. An administrative proceeding on the merits is scheduled to begin on October 26, 2015.

I.

Defendants Steris and Synergy are the second- and third-largest sterilization companies in the world, the largest provider being Sterigenics International LLC (Sterigenics). Sterilization of many healthcare and healthcare-related products is a critical final step in their manufacture; it

is required by the Food and Drug Administration (FDA) to eliminate microorganisms living on or within the manufacturers' products before those products are distributed to end-users in the United States. Foreign regulatory bodies require sterilization of these same products when sold in foreign countries. Only a small number of manufacturers sterilize their own products: the bulk of sterilization is contracted to suppliers like Steris,[1] Synergy and Sterigenics.

Three primary methods of contract sterilization are currently used in the United States: gamma radiation, e-beam radiation, and ethylene oxide gas (EO). Customers choose sterilization methods based on their products' physical characteristics and packaging. Gamma sterilization, which sterilizes by exposing products to the radioactive isotope Cobalt-60, is the most effective and economical option for most healthcare products because of its penetration capabilities. It is the only viable option for dense products (e.g., implantable medical devices) and products packaged in larger quantities. E-beam sterilization, a second type of radiation sterilization, does not penetrate as deeply as gamma radiation, though it can be effective for low-density products sterilized in low volumes. It represents only 15% of all contract radiation sterilization in the United States. EO is a non-radiation form of sterilization that exposes products to gas to kill unwanted organisms. It is effective only if gas diffuses freely through packaging and makes contact with all product surfaces requiring sterilization.

Steris, with twelve gamma facilities across the country, is one of only two U.S. providers of contract gamma sterilization services. Sterigenics, the other gamma provider, operates fourteen U.S. gamma facilities and two U.S. e-beam facilities. Together, these two firms

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[1]In 1997, Steris acquired a medical sterilization company called Isomedix. (Hr'g Tr. 152 (Steeves).) Today, Steris' contract sterilization business is often referred to as Steris Isomedix.

account for approximately 85% of all U.S. contract sterilization services. Synergy, a British company, is the largest provider of e-beam services in the United States,[2] but operates more than thirty-six contract sterilization facilities, primarily gamma facilities, outside the United States. Of particular note are Synergy's two contract sterilization facilities located in Daniken, Switzerland (Daniken): a gamma facility and an x-ray facility. The Daniken x-ray sterilization facility is the only facility in the world providing x-ray sterilization services on a commercial scale.

The FTC alleges that, prior to the proposed merger announced on October 13, 2014, Synergy had been planning to enter the U.S. with an emerging x-ray sterilization technology it hoped would disrupt the current duopoly in the U.S. contract sterilization market, competing directly with Steris' and Sterigenics' gamma sterilization services. According to the FTC, x-ray sterilization is a competitive alternative to gamma sterilization because it has comparable, "and possibly superior," depth of penetration and turnaround times. (Compl. ¶ 4, Doc #: 1.) The FTC claims that, if consummated, the merger would allow Steris to insulate itself against competition with its gamma business. Synergy's planned x-ray sterilization facilities would have targeted Steris' and Sterigenics' gamma sterilization customers, providing them with options for contract sterilization and resulting in lower prices and improved quality.

After months of investigation, the FTC filed this case several days before the proposed merger was to close, contending that the acquisition of Synergy by Steris would violate Section 7 of the Clayton Act, which prohibits mergers "the effect of [which] may be substantially to lessen

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[2]Synergy acquired its U.S. contract sterilization facilities from BeamOne LLC in April 2011. (Tr. 148.)

competition, or to tend to create a monopoly." 15 U.S.C. §§ 18, 45. The FTC sought injunctive relief under Section 13(b), which authorizes the Court to grant preliminary relief if, after considering the FTC's likelihood of success on the merits and weighing the equities, such relief would serve the public interest. 15 U.S.C. § 53(b).

On June 1, 2015, the Court held a teleconference with counsel to determine how to proceed most efficiently in this matter. As a result of discussions, the parties agreed to file a Stipulation and Order wherein Defendants agreed not to consummate the proposed merger until at least four business days after the Court rules on the FTC's motion for a preliminary injunction. (Doc #: 7.) The parties also agreed to provide the Court with a joint proposed expedited schedule for litigating that motion, which the Court issued. (Doc #: 24.)

The Court held a three-day hearing beginning August 17, 2015, during which the following witnesses testified: Joyce Hansen, Vice President of Sterility Assurance at Johnson and Johnson (J & J); David Silor, Principal Sterilization Associate at Zimmer Biomed Orthopedics (Zimmer); Dr. Richard M. Steeves, founder and CEO of Synergy; Andrew McLean, Synergy's CEO of Applied Sterilization Technologies (AST) & Laboratories; Constance Baroudel, one of the outside directors on Synergy's PLC Board; Gaet Tyranski, Synergy's President, AST for the Americas; Gavin Hill, CFO of Synergy; and Walter Roseborough, CEO of Steris. The parties filed simultaneous post-hearing briefs and response briefs. (Doc ##: 77, 78, 80, 81.) The Court, having listened to the evidence and reviewed the briefs, issues this ruling.

(Continued on next page)

II.

Section 7 of the Clayton Act provides that

> No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the county, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

15 U.S.C. § 18. Section 13(b) of the Clayton Act provides that

> [u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, . . . a preliminary injunction may be granted . . . .

15 U.S.C. § 53(b).

"Section 7 is 'designed to arrest in its incipiency . . . the substantial lessening of competition from the acquisition by one corporation of the whole or any part of the stock' or assets of a competing corporation." *United States v. Dairy Farmers of Am., Inc.*, 426 F.3d 850, 858 (6th Cir. 2005) (alteration in original) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957)). In enacting this statute, Congress was concerned with probabilities, not certainties. *Id*. (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)). As District Judge David A. Katz recently explained,

> The "only purpose of a proceeding under Section 13[(b)] is to preserve the status quo until the FTC can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976). The ultimate determination as to a Section 7 violation of the Clayton Act is an "adjudicatory function [ ] vested in the FTC." *Id.*

FTC v. Promedica Health System, Inc., No. 3:11 CV 47, 2011 WL 1219281, at *53 (N.D. Ohio Mar. 29, 2011) (alteration in original). Under 15 U.S.C. § 25, the FTC is authorized to seek an

injunction to enforce Section 7, and it carries the burden of proving a Section 7 violation by a preponderance of the evidence. *See, e.g., U.S. v. H&R Block, Inc.*, 833 F.Supp.2d 36, 48-49 (D.D.C. 2011) (citing 15 U.S.C. § 25).

To show a likelihood of success under Section 13(b), the FTC must "raise questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance, and ultimately by the Court of Appeals." *F.T.C. v. Promedica*, 2011 WL 1219281, at *53, (quoting *FTC v. Butterworth Health Corp.*, 946 F.Supp. 1285, 1289 (W.D. Mich. 1996), *aff'd*, 121 F.3d 708 (6th Cir. 1997)).

According to the FTC, the "actual potential entrant" doctrine specifically addresses this factual scenario: where a potential entrant (i.e., Synergy) merges with a firm already competing in the market (i.e., Steris) and the effect lessens future competition. The FTC asserts that the acquisition of an actual potential competitor violates Section 7 if (1) the relevant market is highly concentrated, (2) the competitor "probably" would have entered the market, (3) its entry would have had pro-competitive effects, and (4) there are few other firms that can enter effectively. (Mem. in Supp. of Mot. for TRO and Prelim. Inj. 6 n.40, Doc #: 5-1.)

Defendants challenge the actual potential entrant doctrine, arguing that it has long been disfavored by numerous courts including the Supreme Court. However, the FTC has clearly endorsed this theory by filing this case, and the administrative law judge will be employing it during the proceeding beginning October 26. Accordingly, in deciding the likelihood of success on the merits, the Court will assume the validity of this doctrine.

Prior to the August 2015 hearing, the Court directed counsel to focus their attention at the hearing on the second prong of the actual potential entrant doctrine, i.e., whether, absent the acquisition, the evidence shows that Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities within a reasonable period of time. For the reasons that follow, the Court concludes that the FTC has failed to carry its burden.

III.

In 2000, Dr. Richard M. Steeves, a biochemistry doctor with a business background, purchased a facility with a controlled environment for the purpose of manufacturing products to prevent surgeons from acquiring HIV. (Hr'g Tr. 188-89 (Steeves).)[3] In 2007, Dr. Steeves acquired a small business in medical device sterilization, which became Synergy. (Id.) Synergy quickly grew from a privately held company with an annual revenue of £750,000 to a publicly traded company with an annual revenue of approximately £440,000,000 today. (Id. at 189.)

The first time Dr. Steeves came across x-ray sterilization technology was at an international radiation conference in 2011. (Hr'g Tr. 194.) Daniken, the only company in the world providing x-ray sterilization services on a commercial scale, made a presentation on this new technology that piqued Dr. Steeves' interest. (Id.) He found that the technology worked, but generally dismissed it "because all the talk at the conference was this was an expensive white elephant." (Id.)

In 2012, Leoni Studer, the company that owned Daniken, put it up for sale. (Hr'g Tr. 194 (Steeves).) Dr. Steeves had one of his senior directors conduct due diligence to determine whether the business would be worth acquiring. (Id. at 194-95.) He learned that Daniken had

[3]Citation to "Hr'g Tr." refers to the August 2015 Hearing Transcript, Doc #: 72.)

two components: a gamma facility and an x-ray facility. (Id. at 195.) At that time, Daniken's gamma facility was running at 75% capacity, while the x-ray facility was running at 22%. (SH-00968554; PX00423-030.) Synergy reached a valuation the directors thought workable based on the gamma business supporting the x-ray business and, "importantly, what we were expecting in terms of a change in interest in x-ray." (Id. at 195.) This predicted increase in customer interest in x-ray was based on the fact that J & J, one of the world's leading manufacturers of medical devices, pharmaceutical and consumer packaged goods, was about to begin the process of making the change from gamma to x-ray sterilization for one of its products (i.e., Surgicel, a blood-clotting agent) at the Daniken facility—setting what Dr. Steeves believed would be "an industry trend" away from gamma and towards x-ray sterilization. (Id.) At the same time, the directors understood that they faced three significant obstacles in bringing this new technology to the U.S. market: lowering the capital costs, understanding the regulatory hurdles involved in transitioning from gamma to x-ray sterilization, and convincing gamma customers to accept and, more importantly, *support* this new technology. (Id. at 195-96.) Based on forecasts predicting the x-ray facility would reach 52% capacity by fiscal year 2015 and 64% by fiscal year 2016, Synergy decided to purchase Daniken. ((SH-00968554; PX00423-030; Hr'g Tr. 653-55 (Hill).)

Synergy's management hierarchy consists of two main boards. (Hr'g Tr. at 148, 190 (Steeves).) The Senior Executive Board (SEB) runs the day-to-day operations, generates business strategies, and makes decisions on investments up to £10,000,000 (approximately $15.5 million). (Id.) As a publicly traded company, Synergy also has a PLC Board of Directors that represents the shareholders, defines the company's business and investment strategies, and

ensures that the company's operational and financial performance respects the shareholders' interests. (Hr'g Tr. 446 (Bouradel), 645 (Hill).) The PLC Board consists of 4 outside directors and 3 inside directors. (Id. at 150 (Steeves).) Together, they have responsibility for governance, signing off on strategy developed by the SEB, and investments over £10,000,000. (Id. at 190.)

At the annual meeting of the combined SEB and PLC boards held in October 2012, Dr. Steeves made a presentation on x-ray technology and Synergy's recent acquisition of Daniken. (Hr'g Tr. 151-55 (Steeves).) Dr. Steeves observed that Synergy could not compete in the U.S. market for contract sterilization services with its gamma, e-beam and EO services, given that Steris and Sterigenics held 83 % of the radiation market and 90% of the EO market. (Id. at 152-53.) He believed that Synergy could only compete with Steris and Sterigenics in the U.S. market by introducing its new x-ray sterilization technology, acquired via its acquisition of Daniken. (Id. at 153.) He pointed out that there were five main hubs in the United States where radiation sterilization is performed, and he hypothesized that Synergy could build a facility in each of those hubs with the prospect of taking more than $120 million of revenue away from Steris and Sterigenics. (Id. at 154.) He recommended that Synergy endeavor to reach an exclusivity agreement with IBA, the only manufacturer of x-ray equipment in the world that could make a machine powerful enough to sterilize medical devices on a commercial scale, to build up to five facilities in the U.S. (Id. at 155.)

Dr. Steeves made a similar presentation to the top Synergy leaders in a conference held in April 2013. (Hr'g Tr.155-56 (Steeves).) Two days later, he hired Andrew McLean to lead the design and project teams for the AST division, beginning in June 2013. (Id. at 157; PX00095-001.) In a letter to McLean dated May 15, 2013 (before McLean came onboard), Dr. Steeves

updated McLean on the status of various AST businesses. (PX00095-001.) With regard to x-ray at Daniken, Dr. Steeves noted his concern over "slow customer conversions." (Id.) However, Dr. Steeves considered x-ray at Daniken to be a "potential game changer" in the U.S. contract sterilization market. (PX00095-002; Hr'g Tr. 157 (Steeves), 274 (McLean).) Although Synergy hadn't run the numbers on x-ray in the United States, he commented that "intuitively I think it could be lower cost than gamma, and would beat the gamma service on every other operating metric. This is one of the key projects I would like you to lead through the design team." (PX00095-002.) In April 2014, McLean was promoted to CEO of AST and Laboratories. (Hr'g Tr. 156 (Steeves).)

McLean was tasked with presenting the U.S. x-ray team's strategy to the combined boards at the November 2013 meeting. (Hr'g Tr. 211 (Steeves).) McLean never made that presentation, however, as it was around that time that Nordion, the world's leading supplier of Cobalt-60 (the energy source for gamma radiation sterilization) and one of only two Cobalt-60 suppliers in North America, became available for acquisition. (Id. at 211-12 (Steeves), 461-62 (Bouradel).) Both Steris and Sterigenics participated in a bidding war for Nordion beginning in the fall of 2013 that culminated in an announcement, on March 31, 2014, that Sterigenics entered into a definitive agreement to acquire Nordion.

Now concerned about Cobalt-60 supply in the hands of Sterigenics and motivated by his belief in x-ray technology, Dr. Steeves decided to explore fully the concept of commercial x-ray sterilization in the U.S. and other parts of the world. (Hr'g Tr. 213 (Steeves).) He directed Andrew McLean to "redouble his efforts and do everything he could to try and get this to work, sort out the three issues that he needed to address in order to allow [Synergy] to bring it in the

United States." (Id.) Those issues are the same impediments Synergy faced when it purchased Daniken: (1) developing a business plan requiring significantly less capital than the 18 million euros it cost Leoni Studer to build Daniken, (2) overcoming customer reluctance to switch sterilization modalities, and (3) obtaining revenue commitments from a base load of customers in the form of take-or-pay contracts. (See also Hr'g Tr.195-197, 202-203 (Steeves).)

Synergy's corporation has three businesses: AST, hospital sterilization services, and a linen business. (Hr'g Tr. 646-47 (Hill).) Synergy has an annual maintenance budget of $40 million, and a discretionary budget of $25 to $40 million for investment purposes. (Id. at 650.) The competition for discretionary cash among the businesses has led Synergy to establish a formal process for deciding which projects to fund.

The first phase of the process is aspirational; a Synergy business (e.g., AST) will come up with an idea for a capital project, and do the research to determine whether it can make a business case that supports the investment of discretionary capital. (Hr'g Tr. 678 (Hill); see also 206 (Steeves) ("[M]ost of the ideas I think probably come from me and my team.").) The project team enters the results of its research into a template, designed by Synergy CFO Gavin Hill, which outputs numbers, or metrics, commonly used by corporations when deciding whether to invest significant capital. (Hr'g Tr. 660-61 (Hill).) The project team will present the business case to the SEB for approval, and may return to the SEB several times before the concept is approved. Once the SEB approves the business case, but before it is submitted to the PLC Board, the business model must undergo a rigorous review by Hill and his corporate finance team, known within the corporation as the "black hat" review. (See generally Hr'g Tr. 206-08, 221 (Steeves); 412-13, 418 (McLean); 446-450 (Bouradel); 678-682 (Hill).) When the business

case is sufficiently "robust," the black hat review commences. (Id. at 681 (Hill).)

The black hat process "is a management term for a two-part review." (Hr'g Tr. 648 (Hill).) The first component is the financial review of "the assumptions underpinning the business case." (Id. at 678-79.) According to Hill, the project team needs to understand what underpins the revenues, benchmark the costs against other facilities, consider the return on sales, and, generally, make sure that the team has thoroughly done its homework and put together a comprehensive business model. (Id. at 679-680.) The second part of the review is the commercial review. It covers a number of areas such as the contracts underpinning the revenues (e.g., take-or-pay contracts, termination clauses, penalty payments) and all aspects of risk (e.g., pension, insurance). (Id. at 680-81.) The black hat review must conclude, and the SEB must approve, the business model before it is presented to the PLC Board. (Id. at 681, 707).

There are a series of metrics, or "hurdle rates," that Hill's team uses to evaluate and compare the expected financial performance of proposed capital projects—measures commonly used by corporations when ranking investments. (Hr'g Tr. 652 (Hill).) Among the metrics is the internal rate of return (IRR), which Synergy targets as 15%. (Id. at 656-675; JDX2859-001, Synergy Group Policies and Governance Manual ¶ 9.3.2.) The IRR is the expected rate of growth from a project over a period to time (Hr'g Tr. 656 (Hill).) It is the cash that is left over after the taxes and operating costs have been removed, which can then be reinvested in the business. (Id. at 659) Synergy considers a project's IRR over a period of seven to ten years maximum, because investors typically have a short-term perspective, with a three-year horizon. (Id. at 659-661.) That a project has an IRR of 15% does not guarantee that it will be approved by the PLC Board. (Id. at 661.) Just as important is the risk profile. (Id. at 662.) Hill testified

that the risk profile is especially important where, as here, Synergy would be considering a capital expenditure (CAPEX) that would consume the company's entire annual discretionary budget. (Id.) Any financial impact from that investment would have a reportable effect on the company's earnings. (Id.)

Another metric is the return on capital employed (ROCE), which Synergy targets at 15%. (JDX2859-002 ¶ 9.3.3; Hr'g Tr. 664 (Hill).) It is the ratio of operating profit to shareholder funds and long-term debt, or a measure of how well the company converts invested capital into profit. (Id.) While the IRR looks at future cash flows, ROCE is a single figure calculation in a single year. (Hr'g Tr. 664 (Hill).) Hill testified that he looks at ROCE as "one of the most important measures for the business . . . as there is an extremely strong correlation between [ROCE] and a company's share price." (Id. at 665.) Under Gavin Hill's five-year leadership, Synergy's ROCE has increased from 10% to 12.4%. (Id. at 669-671.) His short-term goal for Synergy is to reach 15%, and then 20%. (Id. at 668.) To get to 15% ROCE at a company level, Hill requires the businesses, such as AST, to deliver a 30% ROCE. (Id. ("Once you take account of regional costs that are in the business, central overhead that is part of running the business, and good will, we have a large amount of good will on our balance sheet, you then get to 15 percent.").)

Another metric is cash payback, which is the period of time it takes for the operating cashflows of the investment to repay the initial capital outlay. (JDX2869-002 ¶ 9.3.4.) Synergy's target cash payback on all investments is 5 years. (Id.; Hr'g Tr. 667-68 (Hill).)

And last, but certainly not least, Synergy requires revenue commitments from customers who will use the facilities. (Hr'g Tr. 201-02 (Steeves), 680-81 (Hill).) These commitments

typically take the form of take-or-pay contracts in which the customer agrees to provide a volume of products for Synergy to sterilize at some point in the future. (IH Hr'g Tr. 62 (Baran).)[4] In the event the customer does not provide those products, it still has to pay for the services. (Id.) These agreements verify that there is a demand for the services, and support the business cases seeking PLC Board approval. (Hr'g Tr. 208-09 (Steeves), 680-81 (Hill).)

Even if a business model satisfies all the metrics, there is no guarantee the PLC Board will approve it. As Constance Baroudel testified, "the finances are important, but it is also the overall strategy that is important," along with consideration of "shareholder expectations." (Hr'g Tr. 473 (Baroudel).) Furthermore, the PLC Board may not reach a consensus on approving the project. (Id.) Gavin Hill testified,

> So if you ask me would you potentially consider a project that maybe just didn't quite hit your hurdle rates but it was guaranteed to deliver, I may say yes, . . . because I know exactly where we are going to be, and I would much rather that over a project that had a much higher potential return but there was huge speculation in the assumptions and could actually deliver a negative return.

(Hr'g Tr. 691 (Hill).) Additionally, the size of the project matters. (Id.) In a project as large as the U.S. x-ray business case, little risk would be tolerated as Synergy would have to forego "many other projects." (Id.)

In May 2014, McLean made a presentation to the SEB, updating the board on the progress of the U.S. x-ray project. The minutes from that presentation show that McLean continued to analyze "as agreed in the previous SEB meeting" the building of combined e-beam and x-ray facilities; determined the location of Sterigenics U.S. facilities and identified the products being sterilized there; and narrowed to eight the number of U.S. locations under

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[4]Citation to "IH TR." refers to the Investigative Hearing Transcript.

consideration. (PX00099-012, -013.) Again, he expressed his "concern with proceeding with this course of action, as it would be difficult to guarantee getting take or pay contracts to support the financial model for building these facilities." (Id.) In a subsequent letter dated May 29, 2014 to Synergy's COO, Dr. Adrien Coward, McLean further explained his concerns over the project:

> I know I sound like a broken record on this but the message does not seem to be cutting through. . . . The fact of the matter is that building an x-ray facility today would not guarantee conversions tomorrow. As an example Daniken x-ray is only ~25% capacity utilized after more than 3 years. If we did not force customers to move from Daniken and our other gamma sites, then capacity utilization would be only 10%. These are the facts and if we push ahead and build without a proper baseload customer(s) in the US it is to our peril. And of course we do not have the same footprint in the US that would allow us to "force" customers to convert and cross validate and indeed our competitors would be doing everything possible to stop that occurring, creating further delays and barriers. No one is more enthusiastic about getting an x-ray footprint in the US than myself, however it could be a complete disaster.

(JDX1510-001); Hr'g Tr. 379-385 (McLean).)

A more detailed presentation of the U.S. x-ray strategy was presented to the SEB by McLean's subordinate, Chris Fry, in July 2014. (PX00101.) The minutes of the meeting show, among other things, that McLean again raised his concern over the lack of customer financial backing for the project. (PX00101-013.) He reported that "despite there being a lot of interest from customers about [Synergy] building X-ray facilities in America none had yet given an indication that they would be willing to enter into a long term take or pay contract." (Id.) By way of example, he pointed out that "J & J had declined the opportunity to enter into such a contract despite the fact that they were saving 50% of costs and it was only a two-year payback period for the revalidation costs [due to] concern about the risk." (Id.) With regard to x-ray sterilization of medical devices, he observed that "the big concern was the impact of treatment on the form and function of the device." (Id. See also Hr'g Tr. 214-15 (Steeves).) At the

conclusion of the meeting, it was agreed that McLean would present a formal business case at the September 2014 SEB meeting. (PX00101-013.)

Following the July 2014 meeting, McLean tasked Gaet Tyranski, President of AST for the Americas, with preparing the September 2014 presentation. (Hr'g Tr. 511 (Tyranski).) McLean directed Tyranski to generate as many customer letters of interest as possible by the first week in September, to identify two potential U.S. building sites taking into consideration the location of the headquarters, manufacturing, or distribution facilities of the largest medical device manufacturers, and to identify the products manufactured there. (Id. at 504-05.)

In a report circulated to board members prior to the September 2014 meeting, McLean reported that, while a number of major medical manufacturers (J & J, Community Tissue, BD, Stryker Orthopedics, and Bayer) had signed letters of interest in x-ray sterilization services in the U.S., he still had difficulty getting anyone to "bear the risk" of x-ray given that it was new and unproven in the United States. (Hr'g Tr. 307-08 (McLean) (citing PX5771 at 5).) Two days before the September 2014 SEB Meeting, McLean reported to Dr. Steeves and Dr. Coward that he had reached an oral agreement with IBA in which IBA would agree to provide dual x-ray/e-beam sterilization equipment to Synergy exclusively for 10 years for its U.S. operations, provided Synergy would make down payments on the first two x-ray facilities by the end of October 2014.

On September 17, 2014, Tyranski presented the business plan to the SEB. (PX00104-0003 to -00076.) The presentation sought approval for a strategy offering dual x-ray/e-beam sterilization at a network of four to five facilities in the United States. (PX00104-0004, -0027.) Phases 1 and 2 called for the construction of two facilities, one in Indiana and one in Texas, that

would be in operation by fiscal year 2016. (PX00104-0007, -0021.) Phase 2 called for the construction of two to three more facilities beginning in fiscal year 2016, with an expected completion date in fiscal years 2017 or 2018. (PX00104-0007.) The presentation contemplated an investment of approximately $20.2 million for each plant— meaning a capital investment of more than $40 million was required for the first phase of the proposed project alone. (Hr'g Tr. 587 (Tyranski); PX00104-0005; JDX2471-016.).

The September 2014 business plan indicated that the first two plants would offer a combined IRR of 6.51%, and a cash pay-back period of 7.7 years. (PX00104-0037.) The revenue assumptions in the plan were based on achieving a target of 15% of the U.S. gamma market after completion of all five plants (i.e., fiscal year 2018). (PX00104-0005, -0007.) The plan assumed that customers would pay a lower cost for x-ray ($2.50 per cubic foot) versus gamma ($3 to $4). (PX00104-0034.) And it assumed that the first two plants would achieve nearly 100% capacity utilization by the end of year 6.

In fact, the only number that was locked down in this business model were the revenues from the volume of products Synergy planned to transfer from its Lima, Ohio e-beam plant to the new plant for e-beam sterilization. (Hr'g Tr. 406 (McLean).) It was later discovered that the revenue from the Lima plant was counted twice. (Id. at 694-95 (Hill).) Correcting this accounting error reduced the IRR from 6.51% to 3%. (Id.) The evidence shows that all the other numbers upon which the business model was based were the product of guesswork and assumptions.[5] Even with an IRR of 6.5%, McLean knew the SEB would not approve the

[5]Since the team did not have any take-or-pay contracts, they could only guess at the volume of medical devices that might go through the facility. (Hr'g Tr. 405 (McLean).) The 15% market share number was an arbitrary number the team thought Synergy "might" be able to achieve "over a seven-to-ten year time frame." (Id. at 407.) The team plugged in some numbers to show

business model. (Id. at 418 (McLean).) And with an IRR of 6.5% *and* no customer commitments, McLean didn't bother to ask Hill to conduct a black hat review because he knew the model was not ready. (Id. at 418-19.) The business model was never presented to the PLC Board. (Hr'g Tr. 472-73 (Bouradel).)

While the evidence shows that the SEB approved the x-ray/e-beam strategy, the minutes of the meeting reflect considerable concern over the numbers in Tyranski's business model. (JDX2471-018.) Specifically, Gavin Hill commented that "he was surprised . . . the financial model did not look better. The output appeared to be the same as for a gamma facility but given the unproven nature of the technology it was considerably riskier, and it assume[d] that [Synergy] would be able to command a premium price for its services." (Id.) Dr. Steeves advised that he considered the strategy right, but "he had concerns that the economics were not right and that these needed to be looked at again." (Id.) Chris Fry advised that "some of the numbers in the model were guess work." (Id.) Dr. Coward "suggested that rapid work needed to be done to build up the cost base from scratch." (Id.) Yet again, McLean pointed out that "it was difficult to get a base load customer to bear any risk of X-ray given that it is new and unproved in the US." (Id.)

At the PLC Board meeting the next day, outside director Constance Baroudel asked for an update on AST's U.S. strategy. (PX00574-001.) Dr. Coward reported that Daniken, while increasing in capacity utilization, "was also undertaking more work for industrial [non-medical device] customers, as the regulatory process to allow [medical] devices to be sterilised using X-rays was taking longer than originally planned." (PX00574-002.) Dr. Steeves reported that

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that the facility would reach 100% capacity utilization "around year seven or so." (Id. at 411.)

McLean was "working on entering into an exclusivity agreement with IBA to ensure that Synergy was the only outsourced sterilisation provider [that] would supply X-ray equipment in the US." (PX00574-002.) However, "in order to secure this exclusivity it was likely that deposits of €300k each would need to be placed for two X-ray facilities before the end of the financial year." (Id.) Dr. Coward made clear that formal approval for the plan involving four facilities "was **not** being sought at this juncture, just for the deposits on two machines." (PX00574-010.) The PLC Board approved the down payments for the two facilities with IBA. (Id.)

On October 7, 2014, core team members from the United States and Europe attended a kickoff meeting in Florida during which Gaet Tyranski made a presentation he called "Project Endurance." (Hr'g Tr. 525 (Tyranski).) He noted that the U.S. x-ray strategy was approved by the SEB at the September 2014 meeting. (Id. at 526.) He also noted that the SEB identified key actions to be addressed, including further reduction of CAPEX by at least $1.5 million, further work on the facility locations, and finalizing the exclusivity agreement with IBA. (Id. at 527.) At the August 2015 hearing, Tyranski testified that, although he did not mention in his presentation that customer commitments would be needed in order for Project Endurance to go forward, it was understood based on his experience at Synergy. (Id. at 529.)

Less than one week later, on October 13, 2014, Steris announced its proposed merger with Synergy. Notwithstanding this announcement, evidence shows that work on the U.S. x-ray project continued unabated.

On October 21, 2014, Tyranski sent an email to his x-ray team stating that, with the exception of market development expense (e.g., "a Synergy branded new x-ray logo and

campaign when it will likely be Steris in a few months"), the x-ray project was proceeding as planned. (Hr'g Tr. 531-32 (Tyranski).)

On October 30, 2014, McLean reported that he had executed an option contract with IBA giving Synergy until March 31, 2015 (the end of Synergy's fiscal year), to sign purchase agreements with IBA. (Hr'g Tr. 331 (McLean.) McLean testified that, at that time, he was having standing meetings every two weeks with J & J, whose product Surgicel was recently approved by the FDA for x-ray sterilization, prodding them for a take-or-pay contract "or *any* project with J & J for x-ray in the United States." (Id. at 336.) He testified that "the weeks and months drew on and there was nothing." (Id.) Still, he had cause for optimism because J & J continued to express enthusiasm about x-ray, they complained about the sharp increase in prices for Cobalt-60, and there was concern in the industry over Cobalt-60 supply and tightening regulations over disposal of Cobalt-60 and EO residuals. (Id. at 305-07, 339 (McLean).)

On November 4, 2014, Synergy issued its Interim Results for the Six Months Ending 28 September 2014. (PX00580.) On page 4 of the 25-page document, the report provided, with regard to AST,

> We are pleased to announce that we have signed an agreement with IBA for X-ray technology to be deployed in the United States, supplemented by our in-house knowledge and expertise. Our X-ray services are now the fastest growing of our AST technologies, driven by the higher levels of quality, favourable economics and faster processing speed, which helps our customers to reduce their working inventories. Most recently the first FDA approval of a Class III medical device was achieved by one of our major global customer partners, paving the way for further conversions.

(PX00580-004.)

In an earnings call held the next day, Dr. Steeves stated that AST had a really good half year, commenting that

> [t]he strongest growth has been in the Americas along with good growth in Europe from the new facility in Marcoule, France, our x-ray facility in Switzerland and the new capacity acquired with [the Bioster acquisition] . . . Looking forward, there are few further steps we are taking to support growth and including expanding our network in the U.S. as well as expanding the capacity of a number of our facilities around the world. We've also reach an agreement with IBA that will allow us to get started with x-ray in the U.S.

(PX01773-005.)

Meanwhile, Tyranski continued working on locking down numbers for the U.S. x-ray business model, explaining that, if the merger went through, he would just have to re-present his business model to the new combined Steris/Synergy SEB, and that they would probably not build an x-ray facility right next to a Steris gamma facility. (Id. at 532-33, 548-49 (Tyranski).)

The business plan proposed at the September 2014 SEB meeting anticipated that Synergy's e-beam facility in Lima, Ohio would be closed and that the products would be transferred to Synergy's new dual x-ray/e-beam facility. (Hr'g Tr. 539-540 (Tyranski).) On January 19, 2015, Tyranski sent an email to Gavin Hill asking him to sign a lease extension for the Lima facility (to October 2017), so that the new U.S. facility would have base load e-beam revenues while x-ray customers were being developed. (Id.; PX-01265-001.) Hill extended the lease. (Hr'g Tr. 540-41 (Tyranski).)

In November 2014, Tyranski sent Mark Berger, a business development manager, to the Dallas/Fort Worth area to visit numerous proposed locations for an x-ray facility, while Aldo Rodriguez, an accountant, continued discussions over economic incentives that would lower capital costs in building that facility. (Id. at 541-45.) Tyranski testified that the reason for this activity was to nail down costs so that he could present the best business case to the board for approval. (Id. at 545.) Tyranski himself continued discussions with the Miami Valley Research

Park in Dayton, Ohio, regarding incentives and grants that could be offered in locating a facility there—discussions that continued into February 2015. (Id. at 545-49; PX01270.) Tyranski testified that he could not make a decision on committing to a lease until he presented the business case to the SEB again. (Hr'g Tr. 548 (Tyranski).)

The evidence shows that, on October 9, 2014, Tyranski sent an email to his sales staff reminding them to continue to elicit customer letters of interest under the market development strategy and offering $500 bonuses to those who could get a customer to sign up to send their product to Daniken for x-ray testing by November 15, 2014. (Hr'g Tr. 549-551 (Tyranski); PX00244-001.) He subsequently extended the deadline another several months. (Hr'g Tr. 549 (Tyranski).)

The evidence also shows that, despite Synergy's best efforts to advance the x-ray project, news on the economic front worsened. The machine that formed the cornerstone of the September 2014 business plan was IBA's Rhodotron TT300. (Hr'g Tr. 423-28 (McLean); 555-567 (Tyranski).) IBA had represented that its Rhodotron TT300 was a combination x-ray/e-beam machine that could meet Synergy's needs. (Id. at 424 (McLean).) But in late 2014, IBA began expressing a lack of confidence in the TT300, proposing a reconfiguration of the TT1000 with a €250,000 increase in price.[6] (PX00240-003-004. Hr'g Tr. 562 (Tyranski), 422 (McLean).) While the TT300 provided both e-beam and x-ray services, the greater capacity was on the e-beam side. A machine that provided both services was critical to the September 2014 business model because it guaranteed considerable e-beam revenue for years (which would be

[6]The Rhodotron TT1000, the machine that ran x-ray at Daniken, was an x-ray-only machine.

satisfied by the movement of products from the Lima, Ohio e-beam plant to the new facility) while Synergy's U.S. x-ray business developed. (JDX1722-001; JDX1775 at 25, 27.) However, the ultimate goal driving the plan's economics was always the machine's x-ray capacity. (JDX1760-002 (Slide 20).) The machine needed to have more x-ray than e-beam capacity; it required 400 kW and 7 MeV for x-ray, and 100 kW and 10 MeV for e-beam. (JDX1920-001.) The TT300 could not achieve the 400kW power level, and there was no dual-purpose machine in existence capable of reaching those power levels. (Hr'g Tr. 582, 615 (Tyranski).) The evidence shows that the business plan with a 300kW machine would produce 25% less revenue than the TT1000 with 400kW. (PX00240-004.) According to McLean, the one thing he thought "should have been relatively simple just became more and more complex and more and more costly." (Hr'g Tr. 422-23.)

The uncertainty culminated in a meeting in January 2015 attended by principals from Synergy and IBA, during which IBA told Synergy that the price of the systems was "going up." (Hr'g Tr. 426 (McLean).) Tyranski testified that, at the time of that meeting, IBA's price for a TT1000 with 400kW capacity was €5.304 million and the cost of the machine constituted more than 25% of the capital cost for one facility. (Id. at 577-78 (Tyranski).)

In response to a question at the August 2015 hearing, whether IBA gave Synergy an estimate as to how long it would take to design, build and test the system, McLean responded,

> Well, that's—that's a question I never asked, because at that point, I'm getting quite frustrated and disillusioned with the whole thing. It is going nowhere. And in my point of view, if they have never built one, never tested one, did we want to be the guinea pig?
>
> And I remember discussions with my team saying, you know, do we want to be the experiment here in the U.S. and persuade and influence J & J and other top tier customers to come over to us and then have a failure? It had to work."

(Hr'g Tr. 426-27 (McLean).) When the Court asked Tyranski to gauge, in February 2015, his confidence level that IBA could produce the machine at the required power level, he responded, "Their story kept changing so I was skeptical. I was probably more than 50 percent confident that they could ultimately get there *over time*, but there were no guarantees." (Id. at 577 (Tyranski) (emphasis added).) It is undisputed that there is no machine in existence today that is capable of providing both x-ray/e-beam sterilization at the 400kW power level. (Id. at 425 (McLean), 577 (Tyranski).)

On February 24, 2015, McLean sent a declaration to the FTC stating that he was terminating Synergy's U.S. x-ray project, and listing the reasons for doing so. (JDX2655.) He described his team's "top-down, full-court" efforts, and failure, to solicit customer commitments. (Id. at ¶ 2.) He explained that Synergy's sales and marketing efforts began in July 2013, by identifying 185 leading medical device and pharmaceutical manufacturers as potential candidates for x-ray. (Id. at ¶ 6.) For those companies, Synergy began its marketing efforts with sales calls made in conjunction with sales of other AST products, explanatory brochures, webinars, live seminars, tours of Synergy plants, tours of Daniken, and phone calls. (Id. at ¶ 6.) Of those companies, Synergy targeted 34 as the best candidates to generate a viable processing volume to underpin the x-ray strategy. (Id. at ¶ 7.) This was necessary to guarantee the revenues needed for the business model to meet the minimum hurdle rates and obtain SEB and PLC Board approval. (JDX2655 ¶ 8.) McLean provided file folders for each of those companies with contemporaneous documentation of those efforts. (Id. at ¶ 9.) In anticipation of presenting a business case to the SEB in September 2014, the project team continued its efforts to obtain some form of customer commitment to support the business model. (Id. at ¶ 11.) All they were

able to obtain were around six nonbinding letters of interest. (Id.) Following the September 2014 SEB meeting, the project's marketing team continued efforts to obtain customer commitments, to no avail. (Id. at ¶ 12.) As no significant U.S. customers remained to be contacted, McLean concluded that "there [was] no reasonable prospect of customer acceptance for Synergy's X-ray project." (Id. at ¶ 4.)

Attached to McLean's declaration are emails from five of Synergy's top customers stating that they have no present intention of using x-ray sterilization: Covidien/Medtronics ("Although x-ray is interesting to the team, it is not a modality the Covidien Group with Medtronic is actively investigating today."), Boston Scientific ("Xray simply has not proven to have any significant benefit over the big three forms of sterilization to warrant real interest."), J & J ("Per our conversation today, the Business Case for J & J to support transfer of its U.S. gamma processed products (done by 3rd Parties) into a new xray facility near Memphis TN (J & J Distribution Center) does not appear to be compelling."), and Becton Dickinson ("The risk to reward ratio remains stubbornly favorable toward Co60 and Ebeam. . . . The costs in labor, material testing, submissions, reviews, etc., to switch to Xray could approach $400K per product family. Multiplied out by 100s, if not 1000s, for different designs and product families and the investment costs are staggering.") (Respectively, JDX2852, JDX2853, JDX2854, JDX2855.) McLean solicited these communications following his meeting with the FTC on February 17, 2015, when asked for evidence showing that customers had refused to back x-ray *in writing*. (Hr'g Tr. 399 (McLean).) McLean testified that if these customers had said they were really committed to x-ray in the United States, he would not have terminated the project.

> So I wanted to make sure. Remember that myself and my team had put a lot of time and effort, hard work into this, so I wanted to be sure. I asked a direct

question and I got a direct answer.

(Id. at 400.)

That same day, Gaet Tyranski sent an email to his team leaders. (PX00863-003.) Noting that "the FTC inquiry was going down a rat-hole," Tyranski advised, "I do think it's prudent to stop further spend on X-Ray Americas." (Id.) When asked at the August 2015 hearing what he meant by "going down a rat-hole," Tyranski responded, "[The FTC inquiry] was bogging the entire team down. It was burdensome." (Id. at 570.)

Tyranski, who had only been President of AST for the Americas since August 2014, was dealing with numerous other capital projects at the same time he was working on the business case for the U.S. x-ray project (i.e. building a facility in Saxonburg, Pennsylvania, working to obtain approval to build a facility in Northern California, and preparing a business case for greenfield sites in the Carribean). (Hr'g Tr. 585 (Tyranski).) Consequently, he spent no more than 30% of his time on the U.S. x-ray project. He testified that, in discussions with McLean over whether to terminate the project, they knew they were reaching the point where the budget for fiscal year 2016 needed to be set. (Id. at 575.) They were concerned about devoting millions of dollars to the U.S. x-ray project, considering customer interest had not advanced much, there were only a couple of customers sending product to Daniken for testing, and the cost base for the September 2014 business model was not improving. (Id.) They were also mindful that the $40 million investment for phase 1 of the project would consume Synergy's entire discretionary budget for the year. (Id. at 587.)

Today, Daniken's x-ray facility is running at only 25% capacity, and there is no dual x-ray/e-beam sterilization machine in existence that operates at a 400kW capacity.

IV.

The FTC contends that Synergy was poised to enter the U.S. market in Fall 2014 by constructing one or more x-ray facilities, and that the merger with Steris caused Synergy to abandon the effort. As a corollary, the FTC argues that documents created and testimony given after the merger was announced should be viewed with a high degree of suspicion. If the FTC is correct, the evidence should show that if the merger does not go through (either because the parties abandon it or a permanent injunction is issued), Synergy is likely to revive its plans and build one or more x-ray facilities in the U.S. in the near future.

In fact, the evidence shows the opposite in at least three ways. One, while Synergy's PLC Board had endorsed the concept of U.S. x-ray in September 2014, the business plan had not been approved and there were significant obstacles that McLean and Tyranski knew they needed to overcome in order to win approval. Two, the announced merger with Steris in October 2014 had no significant impact on Synergy's plans for U.S. x-ray. McLean and Tyranski continued to mobilize the employees under their direction to try to obtain customer buy-in, to try to bring down the cost of the new facilities, and to work with IBA to develop a dual-capability machine of sufficient power to meet Synergy's needs. Three, it was McLean, and not CEO Steeves, who made the decision in February 2015 to discontinue the U.S. x-ray project after he concluded that there was little to no likelihood of obtaining SEB approval, let alone approval from a combined Synergy/Steris board.

The evidence shows that, at the conclusion of the September 2014 SEB meeting, all that the SEB approved was the U.S. x-ray strategy. The SEB did not have the authority to approve discretionary capital expenditures of more than 10 million pounds. Nor did the PLC Board,

which *does* have the authority to approve discretionary capital expenditures over 10 million pounds, approve the September 2014 business plan. In fact, no business plan was presented to the PLC Board for approval. (Hr'g Tr. 221 (Steeves); PX00574-010.) All that Dr. Steeves requested, and the PLC Board approved, was the expenditure of 300,000 pounds each for down payments on the first two facilities, as that is what IBA demanded in order to enter an exclusivity agreement with Synergy.[7] (Hr'g Tr. 223 (Steeves); (PX00574-010.).)

In order to obtain injunctive relief, the FTC has to show a likelihood of proving at trial that, absent the merger, Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities in the U.S. within a reasonable period of time. The Court concludes, for the following reasons, that the FTC has not met its burden.

A. Customer Commitments

The evidence at the hearing revealed that the most significant reason Synergy opted to discontinue the U.S. x-ray project was lack of customer commitment. According to the FTC, there is no documentation that Synergy solicited customer interest throughout 2014, and in any event, customers continue to be "interested in x-ray sterilization in the United States." (Doc #: 81 at 9.) The Court disagrees.

The evidence shows that Synergy's corporate practice is to secure take-or-pay contracts from customers before making significant capital investments, and this was certainly a significant capital investment. The first phase of the project alone required the expenditure of Synergy's entire annual discretionary budget ($40 million). Despite considerable effort on

[7]Bouradel testified at the August 2015 hearing that the PLC Board didn't even have to approve the down payments, as the total expenditure was less than 10 million pounds.

Synergy's part, as shown by the evidence and described in concise detail in McLean's declaration, not a single medical device customer would sign a take-or-pay contract, and only about 6 of the 185 customers Synergy initially targeted in its sales and marketing campaign would sign even a nonbinding letter of interest.

The evidence, in the form of minutes, emails and testimony, shows that McLean knew he had to obtain take-or-pay contracts or some form of financial commitments in order to support the U.S. x-ray business model; otherwise, the business model underpinning the x-ray strategy would not be approved by the SEB or the PLC Board. In fact, the evidence shows that McLean *repeatedly* raised his concern over the inability to obtain financial backing in any form at every SEB meeting at which the U.S. x-ray strategy was discussed, and expressed his frustration in correspondence with Dr. Coward. The evidence shows that, despite the level of interest expressed by a handful of healthcare products manufacturers in x-ray technology, Synergy could not identify a single customer who would provide the financial commitment required to build x-ray sterilization facilities in the United States. Absent the ability to demonstrate a demand for this service, McLean knew that any business model the x-ray team presented to the SEB or PLC Board would not have been approved. Indeed, McLean testified that he didn't bother to ask Gavin Hill to commence a black hat review of the model because the model just wasn't ready.[8]

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[8]Not only does the FTC challenge that a black hat review of the September 2014 business model would have ended the x-ray strategy, the FTC challenges whether Synergy really has a "black hat" process for reviewing business models at all. However, all of Synergy's witnesses who were questioned about the process testified consistently, if in varying detail, about how the corporate finance team conducts its review of proposed capital projects. (Hr'g Tr. 221 (Steeves); 412-13, 418 (McLean); 448-450 (Bouradel); 678-682 (Hill).) Even the FTC conceded that there is documentary evidence referencing the process. (See Doc #: 81 at 2 n.5.) Regardless of what the corporate financial team's review process is called, there cannot be serious dispute that the type of financial review the team conducts (and the metrics it uses) to evaluate capital investments is not standard business practice in the industry.

McLean knew that the September 2014 model, with one exception, was not based on anything more than assumptions (e.g., premium pricing, revenues, market share). (Hr'g Tr. 406-418 (McLean).)

The testimony of the FTC's own witnesses, Joyce Hansen of J & J and David Silor of Zimmer, demonstrates that their interest in x-ray sterilization in the United States was primarily academic. As Hansen testified, she preferred to remain "totally noncommittal" to Synergy until a laundry list of factors were resolved: a decision on where the x-ray facilities would be located in the United States, what machine would be used, which J & J products might benefit from x-ray sterilization, the volume of those products, the completion of functionality studies, and the approval of regulatory agencies in all countries where the x-ray-sterilized products would be sold.

The evidence shows that after McLean asked Hansen for something in writing to support the business model he was preparing to present to the SEB in September 2014, Hansen submitted a letter expressing, *at best*, lukewarm interest. (JDX1188-022.) After articulating a few reasons why x-ray sterilization is "of interest" to J & J, she explained that the primary barrier in transitioning from gamma to x-ray sterilization is "the additional work required to support the physical / functional product testing, regulatory authority submissions, and personnel time and resources for these activities." (Id.) She concluded that "this letter of interest is intended to be a means of communicating our interest in pursuing the use of X-ray processing *in the future*, and is not intended to commit J & J to processing a volume of product in a facility with Synergy Health." (Id. (emphasis added).)

The evidence shows that Hansen well knew how take-or-pay contracts work and the need for volume commitments before building new facilities. When asked about J & J's Albuquerque, New Mexico gamma sterilization facility, Hansen agreed that, in evaluating whether it made sense to build a new facility, J & J would have to consider how much volume would be put through the facility before building it, otherwise it would not be a good use of J & J's capital. (Hr'g Tr. 71-72 (Steeves).) Furthermore, the evidence shows that J & J had previously entered into a $2.8 million take-or-pay contract with Synergy to build an e-beam sterilization facility in Ireland. (Id. at 204-05.) By the time the plant was completed, another medical device company had apparently built a better device than the product J & J intended to put through the facility, and J & J wrote off the entire investment, leaving Synergy empty-handed. So, Synergy had to rely on the $2.8 million to support its investment until it could bring in additional customers. (Id.)

David Silor, Principal Sterilization Associate at Zimmer, testified that he had discussed x-ray sterilization in the U.S. with Synergy for the past two years. (Hr'g Tr. at 116.) But shortly after Zimmer had agreed to conduct a feasibility study at Daniken, Zimmer initiated a major quality remediation project at the FDA's request. (Hr'g Tr. at 119.) Consequently, its resources were shifted to support those efforts and, to this day, Zimmer has been unable to conduct any x-ray feasibility studies at all. (Hr'g Tr. at 119.)

B. Why No Take-Or-Pay Contracts: Customer Concerns

The evidence shows that the problem obtaining customer commitments had nothing to do with the merits or benefits of x-ray sterilization. Sterilization represents only about 3% of the cost of the medical device. (Hr'g Tr. 381.) This means that even if Synergy could promise a

customer a 30% price savings over gamma sterilization for a product, the conversion would only reduce the product's cost by 1%. On the other side of the ledger was the significant cost of conversion, estimated to be $250,000 to $500,000 per product. (Id. at 438.) The product would need to be tested, then the conversion would need to be approved by the FDA and the foreign counterpart in any foreign country where the product would be sold, then the site would have to be qualified; and then product would have to be put through the facility for validation. As J & J found out, this conversion process could take several years. And if a manufacturer of a medical device had been on the market for ten to forty or more years, it is likely that the regulatory standards for testing and approving these products would have gotten tighter, and the product may no longer be in compliance. (Hr'g Tr. 371-72 (McLean).) Furthermore, any x-ray facilities built in the United States would need contingency processing options, i.e., other qualified facilities where products could be sterilized if the facility needed repair. (Id. at 361.) There are no existing x-ray sterilization facilities in the United States; Synergy's would be the first. A problem in Synergy's facility could leave a customer with no readily-available alternative for sterilizing its products, and any mistake could jeopardize a manufacturer's business reputation and, consequently, its business.

In fact, the documentary evidence shows that on February 24, 2015, despite the considerable efforts of McLean and his team to obtain some kind of customer support endorsing the U.S. x-ray business model, not one customer was willing to do so. There are four emails from leading manufacturers of medical and pharmaceutical products (Covidien/Medtronics, Boston Scientific, J & J, Becton Dickinson) expressing their reasons for not signing up for the U.S. x-ray project, e.g., there is no significant benefit in x-ray sterilization over the other

sterilization modalities, the risk-to-reward ratio favors the other modalities, and the cost of transitioning multiple products from gamma to x-ray is staggering. This was correspondence McLean solicited following his meeting with the FTC on February 17, 2015, when asked for documentary evidence showing that customers had rejected x-ray.

At the August 2015 hearing, the FTC made much of the fact that McLean had solicited J & J's email and had asked Vic Baran, who wrote the email, to go back and look at the numbers again because they did not reflect the numbers McLean had previously discussed with Joyce Hansen regarding the costs involved in obtaining validation, product stability, product functionality and regulatory filings. Vic Baran then sent McLean an email with revised numbers. McLean testified that the costs in the email accurately reflected his discussions with Joyce Hansen and the FTC never called Vic Baran to the stand. In any event, the FTC did not challenge the other emails which clearly showed a lack of interest on the part of industry leaders in backing x-ray sterilization of their products at this time.

The evidence shows that Synergy itself had previously undertaken the black hat process for building a new x-ray sterilization facility in Bradford, U.K. When the Bradford gamma sterilization facility was running out of capacity, Synergy's AST team decided to present two business models to the SEB: one for building a gamma facility and one for building an x-ray facility. (Hr'g Tr. 372 (McLean.) The business models showed that the gamma financials were superior to the x-ray financials, and the project team could not drum up one customer who was willing to back the x-ray business model. (Id. at 373.) In the end, because Synergy had to do "the right thing by [its] shareholders," it built a new gamma facility with higher capacity at the Bradford site. (Id.)

Synergy's experience at Daniken only added to these concerns for several reasons. First, the predicted growth in medical product x-ray sterilization (i.e., 52% capacity by fiscal year 2015) never materialized. Today, Daniken's x-ray facility runs at 25% capacity utilization. Second, most of Daniken's x-ray business is processing non-medical products, and the non-medical business is not the business Synergy prefers to attract. (Hr'g Tr. 385 (McLean) (Synergy's core competence is working "in a highly regulated environment, where you have to deliver an exceptional quality," and the volume is stable with guaranteed revenues.) The evidence shows that over 80% of the product going through Daniken's gamma facility is medical; in contrast, only 5 to 6% of the product going through Daniken's x-ray facility is medical. (Id.) Furthermore, the medical device x-ray business at Daniken is paltry; the $100,000 generated represents only about 2% of Daniken's overall x-ray business. (Id. at 389-393.) The evidence shows that Synergy was unsuccessful in getting its existing gamma customers to convert to x-ray. When Synergy tried to leverage this conversion by telling its Daniken gamma customers that there was little or no remaining capacity at the gamma facility, the customers responded by threatening to go to a competitor's gamma facility. (Id. at 383.) McLean testified, "at one point, we were sterilizing soil, earth, at Daniken x-ray to get product through. That's not what we want." (Id. at 385.)

There was nothing McLean and Tyranski could do to change this paradigm. And of course, any further price reduction Synergy might offer to incentivize its customers would result in lower profit margins and IRR for Synergy.

C. Capital Costs

The evidence shows that, despite Synergy's best efforts, it was unable to harness the capital costs to build x-ray facilities in the United States. Synergy has only $25 to $40 million per year to spend on capital projects. The cost of building two x-ray facilities was estimated to be well over that budget. Because this investment would consume the entire annual discretionary capital budget, little risk could be tolerated. It was clearly incumbent on the project team to lock down real numbers, obtain customer commitments, and lessen capital costs. In short, this particular investment, given its enormity, was a "bet the farm" proposition for Synergy.

As the effort to develop a financial model that more accurately represented the economic realities advanced, the numbers got worse instead of better. The evidence shows that, from the September 2014 board meetings, shortly before the merger was announced, until late February 2015, when the project was abandoned, Synergy's estimates on the cost of building the facilities increased by $2.5 million once actual proposals from contractors were considered. (Invest. Hr'g Tr. 198-199 (Fry); SH00483971 at 10.) By early 2015, it became clear IBA had lost confidence that the TT300, the dual x-ray/e-beam machine on which the team's September 2014 business model was based, would deliver the required 400kW capacity. And the TT1000 with dual x-ray/e-beam technology had never been designed, built, tested or priced. The only certainty about the proposed machine was that it would cost considerably more than the initial business model estimates.

The evidence also shows that the September 2014 business model failed every one of the metrics Synergy uses to rank capital investments. With a few exceptions, the PLC Board

generally will not approve funding a discretionary capital investment without an IRR of 15%.[9] The September 2014 business model showed a 6.51% IRR—a number that included a significant accounting error that reduced the projected IRR to 3%. The erroneous IRR was reached by double-counting revenues from the Lima, Ohio plant, and it was the only number in the business model that was not the product of guesswork and assumptions. The evidence also shows that Synergy's target for ROCE was 15%. To reach this goal, the business seeking discretionary funds (e.g., AST) would have to show a ROCE of 30%. The business model presented at the September 2014 meeting would not hit the target until year 7, lowering the current company ROCE from 12.4% to 11.8%: a reportable consequence that, though seemingly small, would raise red flags for shareholders. (Hr'g Tr. 688, 698 (Hill).) Another metric the model failed to meet was cash payback. Synergy's target cash payback for all investments is no longer than five years. The September 2014 business model reflected a cash payback period of 7.7 years.

D. The Prospect of Building X-ray Facilities in the United States

According to the FTC, the current "interest" that a few customers have expressed in x-ray technology, plus the fact that some healthcare products manufacturers have recently sent a few products to Daniken for testing, shows that Synergy was poised to build x-ray sterilization facilities in the United States in the foreseeable future. The evidence of the FTC's own witnesses shows otherwise.

Hansen was asked at the hearing, if Synergy opened an x-ray sterilization facility in the U.S. tomorrow, would J & J send Surgicel to that facility for sterilization? (Hr'g Tr. 77

[9]The evidence shows that this standard could be relaxed where necessary for health and safety, to meet regulatory requirements, or to prevent the potential loss of a customer. (Hr'g Tr. 701 (Malaysia); 702- 703 (China facility); 703 (health and safety, regulatory).)

(Hansen).) Her response was that both parties would have to go through another series of hoops before doing so, i.e., J & J would have to get regulatory approval for the site, Synergy would have to go through installation and operational qualification, and J & J would have to put its product through the facility and conduct validation testing before sterilizing Surgicel there. (Id.)

Silor testified that Zimmer has not evaluated the potential use of x-ray as a sterilization method for the products it manufactures, it has not performed any feasibility testing with x-ray sterilization, it has not evaluated whether x-ray performs better than gamma for its products, it has not discussed pricing for x-ray sterilization with anyone at Synergy, and it has not analyzed the cost of switching to from gamma to x-ray sterilization in any formal way.

Silor testified that, in order to use a new technology for sterilizing medical devices that does not exist here today, Zimmer would have to do a dose mapping study, a dose setting validation, get the subdose verification level, perform sterility testing on the product, modify the manufacturing routers to indicate that the company is using x-ray instead of gamma, make the FDA submissions on Class 3 medical devices, and perform material shelf-life studies and packaging shelf-life studies. (Hr'g Tr. 130 (Silor).) He acknowledged that evaluating an alternative sterilization modality is a long-term project. (Id. at 131.)

E. The September 2014 Minutes

Much examination and cross-examination at the hearing was devoted to the accuracy of the September 2014 SEB meeting minutes. It is undisputed that Jonathan Turner, who was responsible for taking the minutes, did not transcribe the part of those minutes pertaining to the x-ray presentation until March 2015, when Dr. Steeves was preparing to meet with the FTC over

the proposed merger, and he realized that the portion of the September 2014 meeting minutes addressing the x-ray team's presentation was missing.

The evidence shows that Turner kept his minutes in a 195-page notebook, which he used to transcribe the minutes. The FTC challenged the credibility of the minutes because they were not taken verbatim from Turner's notes. However, as Dr. Steeves pointed out during his testimony, the entire SEB board was there, along with one of Synergy's outside directors, and there is no doubt that the presentation was given, the discussion took place, and the minutes that are contained in the middle of Turner's handwritten book "exist and are real." (Hr'g Tr. 246 (Steeves).) In addition, the presentation of the September 2014 SEB meeting is part of the record, and the testimony solicited at the hearing corroborated the minutes.

F. The November 2014 Earnings Call and Interim Report

The FTC contends that the following statements Synergy reported in November 2014 effectively show that Synergy had publicly committed to building two x-ray facilities in the U.S.: "We are pleased to announce that we have signed an agreement with IBA for X-ray technology to be deployed in the United States, supplemented by our in-house knowledge and expertise," "the first FDA approval of a Class III medical device was achieved by one of our major global customer partners, paving the way for further conversions [of products from gamma sterilization to x-ray]," and "[o]ur X-ray services are now the fastest growing of our AST technologies, driven by the higher levels of quality, favourable economics and faster processing speed." (Pl. FTC's Post-Hr'g Br. at 6-7. Doc #: 78.) However, the fact that they were reported after the merger was announced shows that no one at Synergy viewed the proposed merger with Steris as an impediment to its U.S. x-ray strategy. (Hr'g Tr. 225 (Steeves) (noting, three weeks after the

announcement, that he was trying to support the x-ray team and drum up some enthusiasm for the team's efforts "to get customers aligned with what we were trying to do in the United States." (Id.)

G. Timing

The FTC contends that it is the FTC's investigation—and not the numerous business reasons just articulated and supported by evidence—that caused Synergy to "kill" x-ray in the United States. The Court disagrees.

The timing of the decision to pull the plug on the U.S. x-ray project may actually be the best evidence that it was done for legitimate business reasons, as opposed to anti-competitive ones. If the merger with Steris was going to prevent Synergy from entering the U.S. market, Synergy would have stopped working on the U.S. x-ray project as soon as the merger was announced in mid-October 2014. Instead, following the September 2014 meetings, Synergy, led by McLean and Tyranski, continued to go all out to try to win SEB support for the business plan, and ultimately PLC approval,. The x-ray team continued to court customers, signing them up to get their products tested at Daniken. The team continued their detailed discussions with IBA on the appropriate machine. They made road trips to scout out sites, soliciting incentives from the various cities. The evidence demonstrates that this was not a sham to convince the FTC that Synergy wanted to enter the market; it was legitimate effort by Synergy employees who really wanted the project to succeed, but recognized the hurdles they needed to overcome to win approval. The fact that McLean and Tyranski decided to terminate the project in February 2015, four months after the merger was announced and in the midst of the FTC's investigation,

supports the conclusion that this was a decision reached by the project managers after serious consideration of all the business factors involved.

More likely, the last thing Synergy would have done, if the Steris merger was driving its U.S. x-ray strategy, would have been to pull the plug immediately after meeting with the FTC staff in January 2015 and hearing their objections to the merger, as Synergy had to know that doing so would only have solidified the FTC's position that the merger was driving the decision. Synergy could have kept its x-ray efforts going in order to convince the FTC that the merger with Steris was not going to prevent its entry into the U.S. market.

If Synergy had terminated the U.S. x-ray project when it entered talks with Steris, or when the merger was announced in October 2014, the Court might view this scenario differently. However, the evidence shows that the negotiations between Steris and Synergy had no effect whatsoever on the work of Synergy's U.S. x-ray team. The team continued to seek take-or-pay contracts from customers and there is evidence that Synergy incentivized that effort financially. The team continued to crunch the numbers in the business model, to negotiate concessions with states where they considered building the facilities, and to work diligently with IBA on the machine that would meet Synergy's needs.

In the end, the evidence unequivocally shows that the problems that plagued the development of x-ray sterilization as a viable alternative to gamma sterilization in 2012, when Dr. Steeves purchased Daniken, were the same problems that justified termination of the project in 2015: the failure to obtain customer commitments and the inability to lower capital costs.

(Continued on next page)

V.

Because the Court finds that the FTC has failed to show, by a preponderance of evidence, that it is likely to succeed on the merits in the upcoming administrative trial, its Motion for Preliminary Injunction (**Doc #: 5**) is hereby **DENIED**.

IT IS SO ORDERED.

/s/ Dan A. Polster September 24, 2015
Dan Aaron Polster
United States District Judge

FEDERAL TRADE COMMISSION

Administrative Litigation Following the Denial of a Preliminary Injunction: Policy Statement

AGENCY: Federal Trade Commission.

ACTION: Policy statement, and accompanying Commission statement, with request for public comment.

SUMMARY: The Federal Trade Commission has adopted policies explaining how, after a court had denied preliminary injunctive relief to the Commission, the Commission decides whether administrative litigation should be commenced or, if it has already been commenced, should be continued. While the policies are already in effect, the Commission will receive comment for thirty days, and will thereafter take

such further action as may be appropriate.

DATES: The policy statement was effective on June 21, 1995. Comments will be received until September 5, 1995.

ADDRESSES: Comments should be sent to the Secretary, Federal Trade Commission, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580. Comments will be entered on the public record of the Commission and will be available for public inspection in Room 130 during the hours of 9 a.m. until 5 p.m.

FOR FURTHER INFORMATION CONTACT: William Baer, Director, Bureau of Competition, (202) 326–2932, or Ernest Nagata, Deputy Assistant Director for Policy and Evaluation, Bureau of Competition, (202) 326–2714.

SUPPLEMENTARY INFORMATION: 1. On June 21, 1995, the Commission issued the following statement to accompany its policy statement:

Commission Statement to Accompany Statement of Federal Trade Commission Policy Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction

Introduction

The Federal Trade Commission is charged with ensuring that U.S. consumers are protected from higher prices, lower quality, and lessened innovation that could result from anticompetitive mergers.[1] Historically, the Commission has resolved merger cases through administrative trials or consent orders. In recent times, most of the Commission's antitrust complaints have been settled through administrative consent orders.[2] For those relatively few merger cases in which the Commission has litigated, the Commission's usual practice in recent years has been first to seek a preliminary injunction in federal district court to prevent the consummation of the proposed transaction.[3] The Commission has won most of its challenges at the federal district court level.[4]

There have been five instances in the last ten years in which a federal district court has refused to grant a preliminary injunction sought by the Commission, and the Commission then proceeded with a challenge to the merger in administrative litigation.[5] In such circumstances, the determination to continue a merger challenge in administrative litigation is not, and cannot be, either automatic or indiscriminate. In any given case, the evidence, arguments, and/or opinion from the preliminary injunction hearing may, or may not, suggest that further proceedings would be in the public interest. The Commission's guiding principle is that the determination whether to proceed in administrative litigation following the denial of a preliminary injunction and the exhaustion or expiration of all avenues of appeal must be made on a case-by-case basis.

The Commission is issuing the attached Statement to clarify the process it follows in deciding whether to pursue administrative litigation following denial of a preliminary injunction. The Statement also notes that, if necessary, the Commission will adopt certain procedures to ensure parties to a transaction the opportunity to have their views heard by the Commission before it makes its determination.

In order to place these issues in context, this Statement begins by addressing the value of administrative litigation and why a preliminary injunction proceeding, regardless of its outcome, may not in and of itself provide a sufficient basis for the resolution of complex merger litigation.

The Value of Administrative Litigation

The Federal Trade Commission was created in part because Congress believed that a special administrative agency would serve the public interest by helping to resolve complex antitrust questions. Congress intended that the Commission would play a ''leading role in enforcing the Clayton Act, which was passed at the same time as the statute creating the Commission.'' [6] It was expected that an administrative agency was especially suited to resolving difficult antitrust questions, and that the FTC should be the principal fact finder in the process: it is ''within the Commission's primary responsibility'' to draw inferences of competitive consequences from the underlying facts.[7]

The Commission has fulfilled that special role in a number of important merger cases.[8] Administrative cases provide valuable guidance on how the Commission applies the relevant legal standards and analytical principles as they evolve over time. Application of these standards and principles to concrete factual situations, developed in a full record, can provide insight into why certain mergers are likely to harm competition and result in consumer injury, and why others may not. Especially because the Supreme Court has addressed substantive issues of merger law only rarely in recent decades,[9] and because antitrust law during that time has evolved in response to economic learning, the Commission's opinions have been an important vehicle to provide guidance to the business community on how to analyze complex merger issues.

[1] As used herein, the term ''merger'' includes mergers, acquisitions, joint ventures, and equivalent transactions.

[2] For FY 1990 through FY 1994, the Commission resolved complaints through administrative consent orders, without authorizing either federal court or administrative litigation, in 67% of the merger enforcement actions that the Commission authorized.

[3] For FY 1990 through FY 1994, the Commission authorized preliminary injunction actions in 29% of the merger enforcement actions that it authorized; in 4% of its merger enforcement actions, the Commission authorized administrative trials without first proceeding to federal court for a preliminary injunction.

[4] During the five-year period covered by fiscal years 1990–1994, five out of seven of the Commission's motions for a preliminary injunction were granted. In one case, *FTC v. University Health, Inc.*, 938 F.2d 1206 (11th Cir. 1991), the district court's denial of a preliminary injunction was reversed on appeal. For fiscal years 1985–1989, the Commission was successful in six out of nine motions for a preliminary injunction.

[5] *R.R. Donnelley & Sons*, Dkt. 9243, is currently before the Commission on respondents' appeal from the Initial Decision of the administrative law judge. In *Owens-Illinois, Inc.*, Dkt. No. 9212, the Administrative Law Judge (''ALJ'') found liability but the Commission reversed. 1987–1993 Transfer Binder (CCH) ¶ 22,731 (Sept. 11, 1989) (Initial Decision), *rev.d*, 1987–1993 Transfer Binder (CCH) ¶ 23,162 (Feb. 26, 1992). In *Promodes, S.A.*, Dkt. No. 9928, the administrative complaint was settled. 113 F.T.C. 372 (1990). In *Occidental Petroleum Co.*, Dkt. No. 9205, both the ALJ and the Commission found liability. 1987–1993 Transfer Binder (CCH) ¶ 22,603 (Sept. 30, 1988) (Initial Decision), *aff'd*, 5 Trade Reg. Rep. (CCH) ¶ 23,370 (Dec. 22, 1992), *appeal dismissed pursuant to stipulation and modified order*, 5 Trade Reg. Rep. (CCH) ¶ 23,531 (Jan. 14, 1994). In a fifth case, *Lee Memorial Hospital*, Dkt. No. 9265, the administrative proceeding, which was filed prior to the district court's denial of a preliminary injunction, has been stayed pending appeal.

[6] *Hospital Corp. of America* v. *FTC*, 807 F. 2d 1381, 1386 (7th Cir. 1986), *cert. denied*, 481 U.S. 1038 (1987) (''*HCA*'').

[7] *HCA*, 807 F. 2d at 1386.

[8] For example, the Commission's decision in *Occidental Petroleum* provided important guidance on supply side substitution and coordinated interactions in merger analysis. The Commission's decision in *HCA* explained how coordination could occur in an industry with differentiated and non-homogeneous products. Judge Posner, writing for the Seventh Circuit affirming that decision, called it a ''model of lucidity.'' 807 F. 2d at 1385. The Commission's decision in *American Medical International, Inc.*, 104 F.T.C. 1 (1984) examined in detail the dimensions of price and non-price competition in the hospital industry and discussed efficiencies considerations in analyzing a merger.

[9] The Supreme Court's last opinion on substantive merger law was *United States* v. *General Dynamics Corp.*, 415 U.S. 486 (1974).

Why A Preliminary Injunction Proceeding May Not Be A Sufficient Substitute for Administrative Litigation

If the same value could be achieved through a preliminary injunction proceeding as through administrative litigation, then there would be no reason for the Commission ever to proceed past the preliminary injunction phase. The differences between the two types of proceedings, however, mean that one does not equate with the other.

A preliminary injunction hearing has a limited purpose: to determine whether to enjoin the consummation of a proposed transaction pending a full adjudication on the merits. Thus, the district overseeing a preliminary injunction hearing is not charged with making a final ruling on whether the acquisition in unlawful.

Indeed, there may be an inadequate basis for doing so. Because a preliminary injunction proceeding has a limited purpose, the evidentiary record produced is often limited in scope. A court may not hear any witnesses, but instead may rule solely on the basis of the papers filed by the parties. A preliminary injunction proceeding is generally much shorter in duration than a full trial, and, because of its expedited nature, the thoroughness of the evidentiary presentation and analysis may be less than would be expected in a full trial. Since merger analysis can be a highly complex, fact-intensive undertaking, it may be particularly ill-suited for final resolution on the merits in the abbreviated forum of a preliminary injunction proceeding.

Some commentators have suggested that because the Department of Justice lacks the ability to challenge mergers in the administrative process, the Commission's litigation should be confined to the federal courts in order to bring the two agency's enforcement powers in line with one another. The problem with such an approach is that the significant benefits of administrative litigation outlined above would be lost in such a change in enforcement policy. The business community would be denied the guidance provided by merger decisions based on a complete analysis of a full evidentiary record, and Congress' vision of the FTC's central role in merger enforcement would be subverted.

Nonetheless, the Commission recognizes that automatic pursuit of administrative litigation following denial of a preliminary injunction is not required to serve the public interest. The attached Statement of Policy is intended to clarify the process the Commission follows in determining whether to pursue administrative litigation following denial of a preliminary injunction.

2. On June 21, 1995, the Commission issued the following policy statement:

Statement of Federal Trade Commission Policy Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction

The Commission will assess on a case-by-case basis whether to pursue administrative litigation following the denial of a preliminary injunction.[1] If necessary, the Commission will amend its Rules of Practice [2] in order to facilitate the reconsideration of the public interest in continuing with an administrative case when an administrative complaint has already issued.

As discussed in the Commission Statement to Accompany Statement of Policy Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction, the Commission believes that it would not be in the public interest to forego an administrative trial solely because a preliminary injunction has been denied. Nor would it be in the public interest to require an administrative trial in every case in which a preliminary injunction has been denied. Thus, a case-by-case determination is appropriate. This approach gives the Commission the opportunity to assess such matters as (i) the factual findings and legal conclusions of the district court or any appellate court, (ii) any new evidence developed during the course of the preliminary injunction proceeding, (iii) whether the transaction raises important issues of fact, law, or merger policy that need resolution in administrative litigation, (iv) an overall assessment of the costs and benefits of further proceedings, and (v) any other matter that bears on whether it would be in the public interest to proceed with the merger challenge.

If necessary, the Commission will amend Part 3 of the Commission's Rules of Practice to expedite its review of the issues and determination immediately following the denial of a preliminary injuction and the exhaustion or expiration of all avenues of appeal. The issuance of an administrative complaint during the pendency of a preliminary injunction proceeding will affect only the nature of the procedures under which such considerations will be reviewed, not whether they will be reviewed.

If an administrative complaint has not been issued by the time of the district court's ruling on a preliminary injunction and the exhaustion or expiration of all avenues of appeal, the Commission's consideration of whether to issue an administrative complaint will be conducted under its normal procedures for non-adjudicatory matters. If an administrative complaint has already been issued, the Commission will make its determination within the procedural framework for adjudicatory proceedings under Part 3 of the Commission's Rules of Practice.

The policy articulated in this Statement is applicable to any current and future merger enforcement actions initiated by the Commission under Section 13(b) of the Federal Trade Commission Act. The Commission intends, however, to issue within thirty days a Federal Register notice soliciting public comment on the Commission's policy and, if necessary, setting forth any conforming amendments to Part 3 of its Rules of Practice.

3. The Commission has determined to adopt a new rule, 16 CFR § 3.26, to facilitate review of the public interest in continuing an adjudicative proceeding when, after the adjudicative proceeding has begun, a court denies preliminary injunctive relief in a section 13(b) case brought in aid of the adjudication. Under rule 3.26, which is published elsewhere in this issue, respondents can choose to have such review conducted either within the framework for adjudicative proceedings, or following withdrawal of the administrative case from adjudication.

Also, as noted in footnote 1 of the June 21 policy statement, the principles applicable to administrative merger litigation would apply in the context of non-merger competitive litigation. They are also applicable in the context of consumer protection litigation.

By direction of the Commission, Commissioner Azcuenaga concurring in part and dissenting in part.

Donald S. Clark,

Secretary.

Dissenting Statement of Commissioner Mary L. Azcuenaga Concerning FTC'S Adoption of Rule 3.26 Respecting Administrative Litigation Following Denial of a Preliminary Injunction

On June 26, 1995, the Commission issued a Statement of Policy Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction and an accompanying

[1] Although the focus of this policy statement is merger litigation, similar principles would apply following the denial of a preliminary injunction in the context of non-merger competition litigation.

[2] 16 CFR 3.1 *et seq.*

explanation.[1] These documents reaffirm the Commission's longstanding policy, consistent with Section 5 of the FTC Act, 15 U.S.C. § 45(b), of reconsidering whether to pursue administrative litigation following the denial of preliminary relief by the courts. Section 5 requires that the Commission premise issuance of an adjudicative complaint on finding reason to believe that the law has been violated and that enforcement would be in the public interest. This obligation continues implicitly throughout the proceeding, requiring the Commission to take all reasonable steps to assure itself that an enforcement action, once begun, remains in the public interest. I joined in that Statement.

The Commission now adopts new Rule 3.26 to govern how the agency will proceed if a court denies a requested preliminary injunction pending completion of an administrative adjudication.[2] A central feature of the new rule is that following the court's action, the respondents may choose to have the administrative matter removed from adjudication to permit the parties to discuss with the Commission privately, off the record and ''without the constraints of adjudicative rules,'' [3] the public interest in continuing the adjudication in light of the court's action.[4] Strictly speaking, no revision of the Rules is necessary because existing provisions of the Rules of Practice are sufficient to permit the Commission to address any effect the court's action may have on the public interest in continuing the adjudication.[5] Nevertheless, I have no objection to adopting a new rule to provide specific procedures for reconsidering an administrative adjudication following denial of a preliminary injunction. My difference of opinion is this: I believe that a rule adopted to address this situation should provide that the matter be left in adjudication for any reconsideration by the Commission and that any communication between the parties and the Commission take place on the record.[6]

The Commission opines that complaint counsel will be more candid off the record because they ''will be able to discuss the case without concern that their statements might compromise their litigation position if the case is returned to adjudication.'' [7] It also suggests that the *ex parte* procedure will confer similar benefits on ''respondents (and even third parties).'' [8] It is unclear to me why all this candor cannot and should not take place on the public record.

Traditionally, the Commission acts as a prosecutor up to and including its decision to issue an administrative complaint. As soon as the vote to issue an administrative complaint is complete, the Commission assumes a judicial role with respect to that case, which then is said to be ''in adjudication.'' [9] It should go without saying that the Commission must not allow its prosecutorial role to intrude in any respect in carrying out its deliberative role in an administrative adjudication. Removing a matter from adjudication to chat off the record suggests that there is something that the Commission would prefer that the world not know. It also suggests an unease on the part of the Commission in carrying out its judicial function and an unseemly reluctance to relinquish its prosecutorial role. Although the automatic withdrawal provision may not disadvantage the respondent in any given proceeding, it may well undermine public confidence in the integrity of the Commission's adjudicative process.

Let us consider three scenarios following a court's denial of a preliminary injunction: First, complaint counsel have a strong case, notwithstanding the court's denial of a preliminary injunction. If this is so, complaint counsel can explain why on the record. After the case has been withdrawn from adjudication and reconsidered, presumably the Commission will return the case to adjudicative status. Even if the respondents initiated withdrawing the matter from adjudication, the procedure, in-and-out-and-in adjudication, may create a perception that complaint counsel, speaking off the record, had an unfair advantage. The respondents may believe that had they only known what the staff was saying to the Commission behind closed doors while the case was withdrawn from adjudication, they could have defended more effectively and won a dismissal. After all, the court gave the first round to the respondents on the record.

A second scenario is that the case is weak, and complaint counsel's arguments in support of the complaint are correspondingly weak. The Commission suggests in its **Federal Register** notice that if discussion is held on the record, complaint counsel will be inhibited from pointing to weaknesses in the case for fear that if the Commission disagrees and requires the adjudication to go forward, complaint counsel will be disadvantaged by having conceded the weaknesses of the case on the record. An underlying assumption here is that any weaknesses in the case will remain undiscovered (by the courts, by the respondent and by the administrative law judge), as long as complaint counsel can confide in the Commission off the record. Perhaps more serious, the assumption suggests an abiding lack of confidence in the administrative system of adjudication and the Commission's place in it. Complaint counsel will not be able to avoid the weakness of the case by confiding that fact in secret to the Commission. At most, they might conceal the weakness for a time, a result that ultimately would be wasteful of both government and private resources. Regardless of when during an adjudicative proceeding complaint counsel or the Commission itself discovers a possible weakness in the case, the Commission should base its decision whether to continue the proceeding on publicly available information.

The new rule may lend itself to a public perception that the staff of the Commission has an advantage over targets of enforcement actions because the staff has the secret ear of the Commission. If the staff is permitted secret access to the Commission, a decision to continue an adjudication, particularly one that, based on publicly available information, appears weak, likely would suggest that complaint counsel were able to persuade the Commission to proceed only by ''hiding the ball'' from the respondents. Such a message hardly is consistent with fairness to the respondent or with the

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[1] These materials appear again in this volume of the **Federal Register.**

[2] *See* 15 U.S.C. § 53(b).

[3] Notice of Final Rule with Request for Public Comment, 60 Fed. Reg._____, Slip Notice at 2–3.

[4] I do not oppose the alternative procedure included in the new rule, which expressly authorizes a motion by any respondent to dismiss the complaint in the public interest. Although the alternative procedure is redundant in light of existing Rules 3.22 and 3.23, 16 CFR §§ 3.22 and 3.23 (1995), I do not find it objectionable because the arguments would be presented on the record unless the Commission directs otherwise.

[5] *See, e.g.*, Rule 3.22 governing adjudicative motions and Rule 3.23 governing interlocutory appeals. The Commission also, of course, may act *sua sponte* to seek briefing from the parties or to dismiss the complaint.

[6] Confidential communications between the Commission and its staff before a matter enters adjudication and when the Commission is still carrying out its prosecutorial responsibility make sense. In our system of law, investigational and prosecutorial decisions are protected from public scrutiny. *See* 5 U.S.C. § 552(b)(5). Such confidential communications after the prosecutorial function has concluded with the issuance of a complaint, however, raise issues concerning the exercise by the Commission of its quasi-judicial function.

[7] 60 Fed. Reg. _____, Slip Notice at 4.

[8] *Id.*

[9] At this point, all further communications between the parties (complaint counsel and the respondent(s) are on the record with certain specified exemptions. Rule 4.7, 16 CFR § 4.7.

role of the Commission as an unbiased decisionmaker.[10]

A third scenario is that the case is weak, respondents move to withdraw the matter from adjudication, and complaint counsel file nothing in support of the complaint.[11] In such an instance, the Commission may agree with the respondents and dismiss the adjudication, or it may disagree and order that the proceeding continue. There seems no good reason not to have this occur on the public record. Again, private discussions between the Commission and its staff can create a public perception of unfairness to the respondents arising from apparent complicity between the prosecuting attorneys and the purportedly impartial adjudicators—the very danger the separation of functions requirements of the Administrative Procedure Act and the Commission's *ex parte* rule are designed to avoid.[12]

In addition to undermining the separation of functions at the Commission, the new rule limits the Commission's discretion to decide when individual cases should be in adjudication and remain on the public record. The exercise of discretion in an adjudicative matter is a responsibility of the Commission, not an occasion for apology. This responsibility, which must be carried out consistent with the law and with fundamental fairness, should not be ceded without a reason for doing so. Here, I see none. Both the policy to maintain the separation of deliberative and prosecutorial functions and the appearance of having done so are enhanced when the Commission retains its discretion to determine the appropriate disposition of a motion to withdraw from adjudication. The shifting of a portion of that discretion in favor of the respondents may appear open-minded, but, in the long term, it will disserve the Commission and the public interest.

On balance, the Commission and the public would be better served if the Commission retained its discretion to decide which, if any, cases should be withdrawn from adjudication following denial of a preliminary injunction. The new rule is likely to undermine the integrity of the Commission and its adjudicative process by breaking down the wall between the Commission's prosecutorial and adjudicatory roles in a manner inconsistent with the separation of functions requirement of the Administrative Procedure Act and its own *ex parte* rule.

I dissent.

[FR Doc. 95–19110 Filed 8–2–95; 8:45 am]

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[10] Off-the-record discussions with the respondents, followed by dismissal of the complaint, also may create misperceptions of unfairness and favoritism, with the implication that nonpublic communications that could not bear the light of day influenced the Commission's decision.

[11] This assumes that complaint counsel find themselves unable to make a principled argument in support of the complaint. *See* Jose Calimlin, M.D., Dkt. No. 9199 (June 24, 1986) (''complaint counsel represent the Commission's prosecutorial decision as embodied in the allegations of complaint and in the notice of contemplated relief''); *accord* R.J. Reynolds Tobacco Co., Dkt. No. 9206 (interlocutory order, Dec. 1, 1986); *see also* R.J. Reynolds Tobacco Co. (interlocutory order, Dec. 10, 1986) (purpose of adjudication is ''to subject the Commission's complaint to an adversarial test'').

[12] *See* 5 U.S.C. § 552(d); 16 C.F.R. § 4.7.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of **Steris Corporation** **a corporation,** **and** **Synergy Health PLC** **a corporation.**	**Docket No. 9365** **PUBLIC**

ORDER WITHDRAWING MATTER FROM ADJUDICATION
PURSUANT TO RULE 3.26(c) OF THE COMMISSION RULES OF PRACTICE

On October 1, 2015, the Respondents in this matter filed a Motion to withdraw this matter from adjudication, pursuant to Commission Rules 3.26(b)(1) and 3.26(c), 16 C.F.R. §§ 3.26(b)(1), 3.26(c) (2015). At 11:59 p.m. on October 6, 2015, the time period within which Complaint Counsel could file "an objection asserting that the conditions of [Rule 3.26(b)] have not been met . . ." expired, and no such objection was filed. Accordingly,

IT IS ORDERED, pursuant to Commission Rule 3.26(c), that this matter in its entirety be, and it hereby is, withdrawn from adjudication, and that all proceedings before the Administrative Law Judge be, and they hereby are, stayed.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: October 7, 2015

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Dismisses Complaint against Steris and Synergy

FOR YOUR INFORMATION

October 30, 2015

TAGS: Bureau of Competition | Competition

The Federal Trade Commission has voted unanimously to dismiss its administrative complaint challenging Steris Corporation's proposed $1.9 billion acquisition of Synergy Health plc. The FTC had filed a lawsuit in federal court seeking an injunction to prevent the acquisition from going forward pending the outcome of administrative litigation, but the court denied the motion, and the Commission did not appeal that decision.

"Although we still have competitive concerns about this acquisition, we have concluded that further adjudication would not serve the public interest," the Commission wrote in a statement. The Commission cited the fact that "the district court's denial of preliminary relief would render it difficult for us to craft meaningful relief were we to find the merger unlawful at the conclusion of the administrative proceeding."

Both the federal court complaint and the administrative complaint alleged that the challenged acquisition would violate the antitrust laws by eliminating the likely future competition between Steris's gamma sterilization facilities and Synergy's planned x-ray sterilization facilities in certain regional markets in the United States, thus depriving customers of an alternative sterilization service and additional competition.

The Commission vote to approve the Commission statement and dismiss the administrative complaint was 4-0. (FTC File No. 151 0032; the staff contact is Amy Posner, Bureau of Competition, 202-326-2614)

The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust@ftc.gov, or write to the Office of Policy and Coordination, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave., NW, Room CC-5422, Washington, DC 20580. To learn more about the Bureau of Competition, read Competition Counts. Like the FTC on Facebook, follow us on Twitter, and subscribe to press releases for the latest FTC news and resources.

PRESS RELEASE REFERENCE:
FTC Challenges Merger of Companies That Provide Sterilization Services to Manufacturers

Contact Information

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ftc.gov

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of **Steris Corporation** **a corporation,** **and** **Synergy Health PLC** **a corporation.**	**Docket No. 9365** **PUBLIC**

ORDER RETURNING MATTER TO ADJUDICATION AND DISMISSING COMPLAINT

On October 7, 2015, this matter was withdrawn from adjudication pursuant to Rule 3.26(c) of the Commission Rules of Practice, 16 C.F.R. § 3.26(c). The Commission has now determined to return this matter to adjudication for the sole purpose of dismissing the Complaint. Accordingly,

IT IS ORDERED that this matter be, and it hereby is, returned to adjudication;

and

IT IS FURTHER ORDERED that the Complaint in this matter be, and it hereby is, dismissed.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: October 30, 2015

Statement of the Commission
In the Matter of Steris Corporation and Synergy Health PLC
Docket No. 9365
October 30, 2015

We have voted unanimously today to end the administrative litigation regarding Steris Corporation's acquisition of Synergy Health PLC. Although we still have competitive concerns about this acquisition, we have concluded that further adjudication would not serve the public interest.

This matter involves the merger between Steris and Synergy, the second and third largest sterilization companies in the world. Until recently, Synergy sought to introduce emerging x-ray sterilization technology in the United States to compete with Steris and other providers of sterilization services. The Commission investigated whether the transaction would harm competition by terminating those entry plans.

On May 28, 2015, the Commission voted unanimously to issue an administrative complaint alleging that the transaction violated Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act because it was likely to substantially lessen future competition for contract radiation sterilization services in certain regional markets in the United States. The following day, the Commission asked the United States District Court for the Northern District of Ohio to enjoin the transaction pending the conclusion of the administrative litigation. On September 24, following a hearing, the district court denied our request for injunctive relief. We elected not to appeal that ruling. On October 1, Steris made a motion to withdraw this matter from administrative litigation and to terminate it.[1]

In evaluating whether to dismiss administrative litigation following the denial of a preliminary injunction, the Commission considers the following factors: the district court's findings, any new evidence developed during the preliminary injunction proceeding, whether the transaction raises important issues requiring resolution, the costs and benefits of further litigation, and any other matter that bears on the public interest.[2] Although we still have reason to believe that Steris's acquisition of Synergy is likely to have anticompetitive effects, after considering these factors, we have decided that, on balance, it is appropriate to dismiss this case.

[1] Under Commission Rule 3.26, upon such a motion, an administrative case is automatically removed from adjudication pending a determination by the Commission about whether to proceed with the administrative proceeding, unless Complaint Counsel argues that the motion is procedurally improper. 16 C.F.R. § 3.26(c). Here, Complaint Counsel did not raise any procedural objection.

[2] Fed. Trade Comm'n, Administrative Litigation Following the Denial of a Preliminary Injunction: Policy Statement, 60 Fed. Reg. 39741 (Aug. 3, 1995), *available at* https://www.ftc.gov/sites/default/files/documents/federal_register_notices/administrative-litigation-following-denial-preliminary-injunction-policy-statement/950803administrativelitigation.pdf. The Commission recently affirmed that it will continue to consider these factors. *See* Fed. Trade Comm'n, Revisions to Rules of Practice, 80 Fed. Reg. 15157, 15158 (Mar. 23, 2015), *available at* https://www.ftc.gov/system/files/documents/federal_register_notices/2015/03/150323rulespracticefrn.pdf.

Foremost in our thinking is the fact that the district court's denial of preliminary relief would render it difficult for us to craft meaningful relief were we to find the merger unlawful at the conclusion of the administrative proceeding. In particular, because Steris currently provides contract sterilization services using an alternative technology, gamma radiation, the merged company is unlikely to continue Synergy's efforts to bring x-ray sterilization technology into the United States market. Thus, even if the transaction were found to be anticompetitive following an administrative hearing, it is unlikely that there would be any asset or business to divest that would recreate the competitive environment that likely would have emerged in the absence of the merger, at least for the foreseeable future.

This inability to devise meaningful relief largely negates the potential benefits of continuing the administrative litigation, whereas the costs remain substantial. We therefore conclude that the public interest warrants terminating the administrative litigation.

News Release

STERIS plc Completes Acquisition of Synergy Health

LONDON, U.K. - November 2, 2015 - STERIS plc (NYSE: STE) ("STERIS") announced today that is has completed the previously announced combination of STERIS Corporation and Synergy Health plc ("Synergy"). As a result of the transaction, STERIS Corporation and Synergy are now combined under STERIS. The ordinary shares of STERIS will begin trading on the New York Stock Exchange under STERIS Corporation's historical ticker symbol, "STE" beginning tomorrow, November 3, 2015.

"This combination marks a significant milestone for STERIS, creating a stronger global leader in infection prevention and sterilization, better-positioned to provide comprehensive solutions to medical device companies, pharmaceutical companies, hospitals and other healthcare facilities around the world," said Walt Rosebrough, President and CEO of STERIS.

On Friday, October 30, 2015 the U.S. Federal Trade Commission ("FTC") announced that it has decided to not pursue further administrative proceedings challenging the combination between STERIS Corporation and Synergy, and the FTC has formally dismissed the administrative complaint.

Lazard acted as financial advisor and Wachtell, Lipton, Rosen & Katz and Jones Day acted as legal advisors to STERIS in connection with the combination. Investec Bank plc acted as financial advisor and DLA Piper acted as legal counsel for Synergy.

About STERIS

STERIS's mission is to help our Customers create a healthier and safer world by providing innovative healthcare and life science product and service solutions around the globe. For more information, visit www.steris.com (http://www.steris.com).

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Forward-Looking Statements

This press release may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to STERIS or its industry, products or activities that are intended to qualify for the protections afforded "forward-looking statements" under the Private Securities Litigation Reform Act of 1995 and other laws and regulations. Forward-looking statements speak only as to the date of this press release and may be identified by the use of forward- looking terms such as "may," "will," "expects," "believes," "anticipates," "plans," "estimates," "projects," "targets," "forecasts," "outlook," "impact," "potential," "confidence," "improve," "optimistic," "deliver," "comfortable," "trend", and "seeks," or the negative of such terms or other

variations on such terms or comparable terminology. Many important factors could cause actual results to differ materially from those in the forward-looking statements including, without limitation, disruption of production or supplies, changes in market conditions, political events, pending or future claims or litigation, competitive factors, technology advances, actions of regulatory agencies, and changes in laws, government regulations, labeling or product approvals or the application or interpretation thereof. Other risk factors are described herein and in STERIS's, STERIS Corporation's and Synergy's other securities filings, including Item 1A of STERIS Corporation's Annual Report on Form 10-K for the year ended March 31, 2015 and in Synergy's annual report and accounts for the year ended 29 March 2015 (section headed "principal risks and uncertainties"). Many of these important factors are outside of STERIS's or Synergy's control. No assurances can be provided as to any result or the timing of any outcome regarding matters described in the press release or otherwise with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, cost reductions, business strategies, earnings or revenue trends or future financial results. References to products are summaries only and should not be considered the specific terms of the product clearance or literature. Unless legally required, STERIS does not undertake to update or revise any forward-looking statements even if events make clear that any projected results, express or implied, will not be realized. Other potential risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, (a) STERIS's ability to meet expectations regarding the accounting and tax treatments of the transaction, (b) the possibility that the parties may be unable to achieve expected synergies and operating efficiencies in connection with the transaction within the expected time-frames or at all and to successfully integrate Synergy's operations into those of STERIS, (c) the integration of Synergy's operations into those of STERIS being more difficult, time-consuming or costly than expected, (d) operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients or suppliers) being greater than expected following the transaction, (e) the retention of certain key employees of Synergy being difficult, (f) changes in tax laws or interpretations that could increase our consolidated tax liabilities, including, changes in tax laws that would result in STERIS being treated as a domestic corporation for United States federal tax purposes, (g) the potential for increased pressure on pricing or costs that leads to erosion of profit margins, (h) the possibility that market demand will not develop for new technologies, products or applications or services, or business initiatives will take longer, cost more or produce lower benefits than anticipated, (i) the possibility that application of or compliance with laws, court rulings, certifications, regulations, regulatory actions, including without limitation those relating to FDA warning notices or letters, government investigations, the outcome of any pending FDA requests, inspections or submissions, or other requirements or standards may delay, limit or prevent new product introductions, affect the production and marketing of existing products or services or otherwise affect STERIS'sperformance, results, prospects or value, (j) the potential of international unrest, economic downturn or effects of currencies, tax assessments, adjustments or anticipated rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs, (k) the possibility of reduced demand, or reductions in the rate of growth in demand, for STERIS's products and services, (l) the possibility that anticipated growth, cost savings, new product acceptance, performance or approvals, or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with STERIS's businesses, industry or initiatives including, without limitation, those matters described in STERIS Corporation's Form 10-K for the year ended March 31, 2015 and other securities filings, may adversely impact STERIS's or Synergy's performance, results, prospects or value, (m) the possibility that anticipated financial results or benefits of recent acquisitions, including the transaction, or of STERIS's restructuring efforts will not be realized or will be other than anticipated and (n) the effects of the contractions in credit availability, as well as the ability of STERIS's Customers and suppliers to adequately access the credit markets when needed.

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