

MERGER ANTITRUST LAW

Unit 10: Steris/Synergy Health

Class 19

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Fall 2026

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Potential Competition Framework



Merger Guidelines

U.S. Department of Justice and the Federal Trade Commission

Issued: December 18, 2023

Guideline 4: Mergers Can Violate the Law When They Eliminate a Potential Entrant in a Concentrated Market. The Agencies examine whether, in a concentrated market, a merger would (a) eliminate a potential entrant or (b) eliminate current competitive pressure from a perceived potential entrant.

2.4. Guideline 4: Mergers Can Violate the Law When They Eliminate a Potential Entrant in a Concentrated Market.

Mergers can substantially lessen competition by eliminating a potential entrant. For instance, a merger can eliminate the possibility that entry or expansion by one or both firms would have resulted in new or increased competition in the market in the future. A merger can also eliminate current competitive pressure exerted on other market participants by the mere perception that one of the firms might enter. Both of these risks can be present simultaneously.

A merger that eliminates a potential entrant into a concentrated market can substantially lessen competition or tend to create a monopoly.²¹ The more concentrated the market, the greater the magnitude of harm to competition from any lost potential entry and the greater the tendency to create a monopoly. Accordingly, for mergers involving one or more potential entrants, the higher the market concentration, the lower the probability of entry that gives rise to concern.

²⁰ See *H.J. Heinz Co.*, 246 F.3d at 724.

²¹ *United States v. Marine Bancorp.*, 418 U.S. 602, 630 (1974). A concentrated market is one with an HHI greater than 1,000 (See Guideline 1, n.15).

2.4.A. Actual Potential Competition: Eliminating Reasonably Probable Future Entry

In general, expansion into a concentrated market via internal growth rather than via acquisition benefits competition.²² Merging a current and a potential market participant eliminates the possibility that the potential entrant would have entered on its own—entry that, had it occurred, would have provided a new source of competition in a concentrated market.

To determine whether an acquisition that eliminates a potential entrant into a concentrated market may substantially lessen competition,²³ the Agencies examine (1) whether one or both²⁴ of the merging firms had a reasonable probability of entering the relevant market other than through an anticompetitive merger, and (2) whether such entry offered a substantial likelihood of ultimately producing deconcentration of the market or other significant procompetitive effects.²⁵

Reasonable Probability of Entry. The Agencies' starting point for assessment of a reasonable probability of entry is objective evidence regarding the firm's available feasible means of entry, including its capabilities and incentives. Relevant objective evidence can include, for example, evidence that the firm has sufficient size and resources to enter; evidence of any advantages that would make the firm well-situated to enter; evidence that the firm has successfully expanded into similarly situated markets in the past or already participates in adjacent or related markets; evidence that the firm has an incentive to enter; or evidence that industry participants recognize the company as a potential entrant. This analysis is not limited to whether the company could enter with its pre-merger production facilities, but also considers overall capability, which can include the ability to expand or add to its capabilities on its own or in collaboration with someone other than the acquisition target.

Subjective evidence that the company considered entering absent the merger can also indicate a reasonable probability that the company would have entered without the merger. Subjective evidence that the company considered organic entry as an alternative to merging generally suggests that, absent the merger, entry would be reasonably probable.

Likelihood of Deconcentration or Other Significant Procompetitive Effects. New entry can yield a variety of procompetitive effects, including increased output or investment, higher wages or improved working conditions, greater innovation, higher quality, and lower prices. If the merging firm had a reasonable probability of entering a highly concentrated relevant market, this suggests benefits that would have resulted from its entry would be competitively significant, unless there is substantial direct evidence that the competitive effect would be *de minimis*. To supplement the suggestion that new entry yields procompetitive effects, the Agencies will consider projections of the potential entrant's

²² See *Ford Motor Co. v. United States*, 405 U.S. 562, 587 (1972) (referring to the “typical[]” competitive concern when “a potential entrant enters an oligopolistic market by acquisition rather than internal expansion” as being “that such a move has deprived the market of the pro-competitive effect of an increase in the number of competitors”).

²³ Harm from the elimination of a potential entrant can occur in markets that do not yet consist of commercial products, even if the market concentration of the future market cannot be measured using traditional means. Where there are few equivalent potential entrants, including one or both of the merging firms, that indicates that the future market, once commercialized, will be concentrated. The Agencies will consider other potential entrants' capabilities and incentives in comparison to the merging potential entrant to assess equivalence.

²⁴ *United States v. Penn-Olin Chemical Co.*, 378 U.S. 158 (1964) (holding that a merger between two firms, each or both of which might have entered the relevant market, could violate Section 7).

²⁵ See *id.* at 175-76; *Marine Bancorp.*, 418 U.S. at 622, 633 (“[T]he proscription expressed in § 7 against mergers ‘when a “tendency” toward monopoly or [a] “reasonable likelihood” of a substantial lessening of competition in the relevant market is shown’ applies alike to actual- and potential-competition cases.” (quoting *Penn-Olin*, 378 U.S. at 171)); see also *Yamaha Motor Co. v. FTC*, 657 F.2d 971, 980-981 (8th Cir. 1981) (acquisition of potential entrant violated Section 7).

competitive significance, such as market share, its business strategy, the anticipated response of competitors, or customer preferences or interest.

A merger of two potential entrants can also result in a substantial lessening of competition. The merger need not involve a firm that has a commercialized product in the market or an existing presence in the same geographic market. The Agencies analyze similarly mergers between two potential entrants and those involving a current market participant and a potential entrant.

2.4.B. Perceived Potential Competition: Lessening of Current Competitive Pressure

A perceived potential entrant can stimulate competition among incumbents. That pressure can prompt current market participants to make investments, expand output, raise wages, increase product quality, lower product prices, or take other procompetitive actions. The acquisition of a firm that is perceived by market participants as a potential entrant can substantially lessen competition by eliminating or relieving competitive pressure.

To assess whether the acquisition of a perceived potential entrant may substantially lessen competition, the Agencies consider whether a current market participant could reasonably consider one of the merging companies to be a potential entrant and whether that potential entrant has a likely influence on existing competition.²⁶

Market Participant Could Reasonably Consider a Firm to Be a Potential Entrant. The starting point for this analysis is evidence regarding the company's capability of entering or applying competitive pressure. Objective evidence is highly probative and includes evidence of feasible means of entry or communications by the company indicating plans to expand or reallocate resources in a way that could increase competition in the relevant market. Objective evidence can be sufficient to find that the firm is a potential entrant; it need not be accompanied by any subjective evidence of current market participants' internal perceptions or direct evidence of strategic reactions to the potential entrant. If such evidence is available, it can weigh in favor of finding that a current market participant could reasonably consider the firm to be a potential entrant.

Likely Influence on Existing Rivals. Direct evidence that the firm's presence or behavior has affected or is affecting current market participants' strategic decisions is not necessary but can establish a showing of a likely influence. Even without such direct evidence, circumstantial evidence that the firm's presence or behavior had an effect on the competitive reactions of firms in the market may also show likely influence. Objective evidence establishing that a current market participant could reasonably consider one of the merging firms to be a potential entrant can also establish that the firm has a likely influence on existing market participants. Subjective evidence indicating that current market participants—including, for example, customers, suppliers, or distributors—internally perceive the merging firm to be a potential entrant can also establish a likely influence.

2.4.C. Distinguishing Potential Entry from Entry as Rebuttal

When evaluating a potentially unlawful merger of current competitors, the Agencies will assess whether entry by other firms would be timely, likely, and sufficient to replace the lost competition using the standards discussed in Section 3.2. The existence of a perceived or actual potential entrant may not meet that standard when considering a merger between firms that already participate in the relevant market. The competitive impact of perceived and actual potential entrants is typically attenuated

²⁶ See *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 533-36 (1973); *Marine Bancorp.*, 418 U.S. at 624-25.

compared to competition between two current market participants. However, because concentrated markets often lack robust competition, the loss of even an attenuated source of competition such as a potential entrant may substantially lessen competition in such markets. Moreover, because the Agencies seek to prevent threats to competition in their incipiency, the likelihood of potential entry that could establish that a merger's effect "may be" to substantially lessen competition will generally not equal the likelihood of entry that would rebut a demonstrated risk that competition may be substantially lessened.

Mylan/Perrigo



FEDERAL TRADE COMMISSION
 PROTECTING AMERICA'S CONSUMERS

FTC Requires Mylan to Sell Rights to Seven Generic Pharmaceuticals as a Condition of Acquiring Perrigo Company

Divestitures Will Preserve Competition in U.S. Markets for Seven Generic Drugs

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FOR RELEASE

November 3, 2015

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Mylan N.V. has agreed to sell the rights and assets related to seven generic drugs in order to settle FTC charges that its proposed acquisition of Perrigo Company plc would be anticompetitive.

Both companies market generic drugs globally, and according to the FTC complaint, as originally proposed, the acquisition would likely harm competition in U.S. markets for seven generic pharmaceutical products. The settlement order preserves competition by requiring Mylan to divest the rights and assets in these product markets to the New Jersey-based generic pharmaceutical company Alvogen Group Inc.

The complaint alleges that the proposed acquisition would likely have harmed current competition in U.S. markets for four generic drugs. In these markets, both Mylan and Perrigo either are currently selling the drugs, or have approval of the Food and Drug Administration to do so:

- **Bromocriptine mesylate** is used to treat conditions including type 2 diabetes and Parkinson's disease.
- **Clindamycin phosphate/benzoyl peroxide** is used to treat acne.
- **Liothyronine sodium** is used to treat hypothyroidism and to treat or prevent enlarged thyroid glands.
- **Polyethylene glycol 3350** is a laxative used to treat occasional constipation.

The FTC's settlement also will preserve future competition for three generic drugs. According to the complaint, the proposed acquisition would eliminate at least one likely future entrant from a very limited pool of future entrants in each of these markets:

- **Acyclovir** is used to slow the growth and spread of the herpes virus in the body.
- **Hydromorphone hydrochloride** is used to treat moderate to severe pain in narcotic-tolerant patients.
- **Scopolamine** prevents symptoms associated with motion sickness and helps patients recover from anesthesia and surgery.

The proposed buyer, Alvogen, has the necessary resources, financial and technical capabilities, and experience marketing generic pharmaceutical products to replace successfully the competition that otherwise would have been lost through the proposed acquisition.

To ensure that the divestitures succeed, the proposed order requires Mylan to provide Alvogen with transitional services, including technical assistance. Further details about the divestitures are set forth in the analysis to aid public comment for this matter.

The Commission vote to issue the complaint and accept the proposed consent order for public comment was 4-0. The FTC will publish the consent agreement package in the Federal Register shortly. The agreement will be subject to public comment for 30 days, beginning today and continuing through December 3, 2015, after which the Commission will decide whether to make the proposed consent order final. Comments can be filed electronically or in paper form by following the instructions in the "Supplementary Information" section of the Federal Register notice.

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. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to \$16,000 per day.

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 Approves Modified Consent Order for Mylan N.V.

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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 McSweeney

In the Matter of

MYLAN N.V.,
 a company.

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) **Docket C-4557**
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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Mylan N.V. (“Mylan”), a company subject to the jurisdiction of the Commission, has made an offer to acquire the voting securities of Perrigo Company plc (“Perrigo”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Mylan N.V. is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317.

2. The Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. ACQUIRED COMPANY

3. Perrigo is a company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.
4. Perrigo is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

5. On September 14, 2015, Mylan launched a tender offer to acquire all outstanding ordinary shares of Perrigo pursuant to a cash-and-stock offer valued according to public sources at approximately \$27 billion (the “Acquisition”).

IV. THE RELEVANT MARKETS

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:
 - a. acyclovir ointment;
 - b. bromocriptine mesylate tablets;
 - c. clindamycin phosphate/benzoyl peroxide gel;
 - d. hydromorphone hydrochloride extended release tablets;

- e. liothyronine sodium tablets;
 - f. polyethylene glycol 3350 over-the-counter (“OTC”) oral solution packets; and
 - g. scopolamine extended release transdermal patches.
7. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

8. Acyclovir is used to slow the growth and spread of herpes virus in the body. Two firms, Mylan and Amneal Pharmaceuticals LLC, currently hold approved U.S. Food and Drug Administration (“FDA”) Abbreviated New Drug Applications (“ANDAs”) for generic acyclovir 5% ointment. Allergan plc (“Allergan”) also sells the authorized generic version for acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter the generic acyclovir market in the near future. The Acquisition would reduce the number of likely future suppliers for generic acyclovir 5% ointment.
9. Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson’s disease, neuroleptic malignant syndrome, and hyperprolactinemia. In the United States, three companies have approved ANDAs for generic bromocriptine mesylate 2.5 mg tablets: Mylan; Perrigo; and Sandoz AG. The Acquisition would reduce the number of firms capable of supplying generic bromocriptine mesylate 2.5 mg tablets from three to two.
10. Clindamycin phosphate 1%/benzoyl peroxide 5% gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. In the United States, only Mylan markets generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received ANDA approval from the FDA and expects to begin supplying generic clindamycin phosphate 1%/benzoyl peroxide 5% gel in the near future. The Acquisition would combine the only two approved ANDA holders for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel.
11. Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. In the United States, only Perrigo and Allergan hold approved ANDAs to sell generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths. Mallinckrodt plc also sells an authorized generic version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter the market in the near future. As a result, the

Acquisition would reduce the number of future suppliers of generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths.

12. Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, three suppliers provide 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets: Mylan; Perrigo; and SigmaPharm Laboratories, LLC. The Acquisition would increase concentration in this market and reduce the number of suppliers of 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets from three to two.
13. Polyethylene glycol 3350 (“PEG 3350”) is a laxative used to treat occasional constipation. The market for generic PEG 3350 OTC oral solution 17gm packets is highly concentrated with only Mylan, Perrigo, and Gavis Pharmaceuticals, LLC actively supplying the market. The Acquisition would therefore reduce the number of suppliers in this market from three to two.
14. Scopolamine prevents nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG sells a branded scopolamine extended release (1 mg/72 hours) transdermal patch, Transderm Scop. Only Perrigo holds an approved ANDA to sell generic scopolamine extended release (1 mg/72 hours) transdermal patch. Mylan is one of a limited number of suppliers likely to enter this market in the near future. As a result, the Acquisition would reduce the number of likely future suppliers of generic scopolamine extended release (1 mg/72 hours) transdermal patches.

VI. ENTRY CONDITIONS

15. Entry into the relevant markets described in Paragraphs 6 and 7 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Mylan and Perrigo and reducing the number of independent significant competitors in the markets for generic (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets, thereby: (a) increasing the likelihood that Mylan would be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating future competition between Mylan and Perrigo and reducing the number of generic competitors in the markets for (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

17. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this second day of November, 2015, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL:

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT
*In the Matter of Mylan N.V., File No. 151-0129***

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Mylan N.V. (“Mylan”) that is designed to remedy the anticompetitive effects resulting from Mylan’s acquisition of Perrigo Company plc (“Perrigo”). Under the terms of the proposed Consent Agreement, Mylan is required to divest to Alvogen, Inc. (“Alvogen”) all of its rights and assets to the following generic pharmaceutical products: (1) acyclovir ointment; (2) bromocriptine mesylate tablets; (3) clindamycin phosphate/benzoyl peroxide gel; (4) hydromorphone hydrochloride extended release tablets; (5) liothyronine sodium tablets; (6) polyethylene glycol 3350 over-the-counter (“OTC”) oral solution packets; and (7) scopolamine extended release transdermal patches.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

On September 14, 2015, Mylan launched a hostile tender offer to gain a controlling interest in Perrigo. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current and future competition in seven generic pharmaceutical markets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

A generic pharmaceutical drug contains the same active ingredient as the brand name product, but typically at a much more affordable price. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product typically acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, generic suppliers compete only against each other.

Mylan’s proposed acquisition of Perrigo will lessen competition in seven concentrated generic pharmaceutical product markets by reducing the number of current or future suppliers competing in each market. The proposed acquisition will reduce current competition in four generic pharmaceutical markets: (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets.

- Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson's disease, neuroleptic malignant syndrome, and hyperprolactinemia. The market for generic 2.5 mg bromocriptine mesylate tablets is highly concentrated with only three current suppliers: Mylan, Perrigo, and Sandoz AG. Absent a remedy, the proposed transaction would consolidate the market from three to two suppliers.
- Clindamycin phosphate/benzoyl peroxide gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. Today, only Mylan supplies the market with generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received FDA approval for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel and is poised to start supplying the market in the near future. As a result, the proposed transaction would reduce the number of generic clindamycin phosphate 1%/benzoyl peroxide 5% gel suppliers from two to one.
- Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, only three suppliers provide generic liothyronine sodium tablets in the 0.005 mg, 0.025 mg, and 0.05 mg strengths: Mylan, Perrigo, and SigmaPharm Laboratories, LLC. The proposed transaction would further consolidate an already highly concentrated market, leaving two suppliers post-transaction.
- Polyethylene glycol 3350, a laxative, is an OTC oral solution packet used to treat occasional constipation. In the 17 gm/packet OTC market, Mylan, Perrigo, and Gavis Pharmaceuticals, LLC, are the only active suppliers in the market. As a result, the proposed transaction would consolidate the number of active suppliers of generic polyethylene glycol 3350 OTC oral solution packets from three to two.

Additionally, the proposed acquisition will reduce future competition in three generic pharmaceutical markets: (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches. In each of these markets, either Mylan or Perrigo is a likely new entrant in the near future. Without a remedy, the proposed acquisition would eliminate an independent entrant into each market, likely depriving customers of the significant cost savings that result when an additional generic supplier enters a concentrated market.

- Acyclovir ointment is a topical product used to slow the growth and spread of the herpes virus. Mylan and Amneal Pharmaceuticals LLC currently hold ANDAs and supply acyclovir 5% ointment. Allergan plc ("Allergan") also sells an authorized generic version of acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter this market in the near future.
- Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. Perrigo and Allergan hold ANDAs for 8 mg, 12 mg, and 16 mg extended release tablets. In addition, Mallinckrodt plc markets an authorized generic

version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter this market in the near future.

- Scopolamine transdermal patches prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG currently markets the branded version, Transderm Scop, which is available as a 1 mg/72 hour extended release transdermal patch. Perrigo holds the only approved ANDA for the generic version of Transderm Scop. Mylan is one of a limited number of other suppliers likely to enter this market in the near future. As there is no generic version of Transderm Scop on the market today, it is likely that the price for scopolamine transdermal patches would significantly decrease with the onset of generic competition. Without a remedy, the proposed acquisition would eliminate the price reductions that would likely have accompanied Mylan's independent entry into this market.

II. Entry

Entry into each of these generic pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating current or future competition between Mylan and Perrigo in these seven concentrated markets. In each of these markets, Mylan and Perrigo are two of a limited number of current or likely future suppliers in the United States. Market participants characterize each of the markets as a current or likely future commodity market, in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Mylan and Perrigo currently compete likely would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Mylan is required to divest to Alvogen its rights to the seven relevant products. Alvogen is an international pharmaceutical company, with commercial operations in thirty-four countries. Its business focuses on developing, manufacturing, and distributing generic, branded, and OTC

pharmaceutical products. Mylan must accomplish the divestitures to Alvogen and relinquish its rights to these products no later than thirty days after the proposed acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and to divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee if Mylan fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan must provide transitional services to Alvogen to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable Mylan employees. Mylan must also provide Alvogen with a supply of the divested products while Mylan transfers manufacturing technology to Alvogen or its designated manufacturer. The goal of the transitional services is to ensure that Alvogen will be able to operate independent of Mylan in the manufacture and sale of the divested products. Nothing in the Consent Agreement, however, precludes Alvogen from sourcing active pharmaceutical ingredients or other divestiture product inputs from Mylan on a negotiated basis.

As Alvogen was unable to perform due diligence on the Perrigo products at issue, Mylan divested its own on-market, generic acyclovir ointment product rather than Perrigo's product in development. Because the competition that is preserved by the proposed Consent Agreement will only occur when the Perrigo product is launched, the proposed Order permits Mylan to retain the right to sell acyclovir ointment through a license from Alvogen until thirty days after Mylan receives approval for the Perrigo ANDA, but for no longer than three years. This provision is designed to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir ointment ANDA but also ensures Mylan's continued incentive to develop and launch the Perrigo product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Medtronic/Covidien

Medtronic to Acquire Covidien for \$42.9 billion in Cash and Stock

June 15, 2014 6:29 PM CT



Creates a Medical Technology and Services Company with a Comprehensive Product Portfolio and Broad Global Reach that is Better Able to Improve Healthcare Outcomes

Meaningfully Accelerates Medtronic's Core Strategies of Therapy Innovation, Globalization and Economic Value

Combined Revenue of \$27 Billion, including \$3.7 Billion from Emerging Markets

Transaction Expected to be Accretive to Medtronic Cash Earnings in FY2016 and Significantly Accretive thereafter

Medtronic Commits to \$10 Billion in Additional U.S. Technology Investments Over 10 Years

MINNEAPOLIS AND DUBLIN - June 15, 2014 - Medtronic, Inc. (NYSE: MDT), a global leader in medical technology, services and solutions, and Covidien plc (NYSE: COV), a global healthcare technology and medical supplies provider, today announced that they have entered into a definitive agreement under which Medtronic has agreed to acquire Covidien in a cash-and-stock transaction valued at \$93.22 per Covidien share, or a total of approximately \$42.9 billion, based on Medtronic's closing stock price of \$60.70 per share on June 13, 2014.

Once the transaction is completed, Medtronic will have significantly advanced its position as the world's premier medical technology and services company. The combined company will have a comprehensive product portfolio, a diversified growth profile and broad geographic reach, with 87,000 employees in more than 150 countries. The Boards of Directors of both companies have unanimously approved the transaction.

"We are excited to reach this agreement with Covidien, which further advances our mission to alleviate pain, restore health and extend life for patients around the world," said Omar Ishrak, Chairman and Chief Executive Officer of Medtronic. "This acquisition will allow Medtronic to reach more patients, in more ways and in more places. Our expertise and portfolio of services will allow us to serve our customers more efficiently and better address the demands of the current healthcare marketplace. We also look forward to welcoming the Covidien team to Medtronic and working together to improve healthcare outcomes globally."

"Covidien and Medtronic, when combined, will provide patients, physicians and hospitals with a compelling portfolio of offerings that will help improve care and surgical performance," said José E. Almeida, Chairman, President and Chief Executive Officer of Covidien. "This transaction provides our shareholders with immediate value and the opportunity to participate in the significant upside potential of the combined organization. I'd like to thank our 38,000 employees whose hard work and dedication has enabled Covidien to deliver innovative health solutions that improve patient outcomes."

Strategic Rationale

The combination with Covidien supports and accelerates Medtronic's three fundamental strategies:

- **Therapy Innovation:** With its expanded portfolio of innovative products and services, Medtronic will be a preeminent leader in delivering therapy and procedural innovations to address the major disease states impacting patients and healthcare costs around the world. Covidien has an impressive portfolio of industry-leading products that enhance Medtronic's existing portfolio, offer greater breadth across clinical areas, and create exciting entry points into new therapies.
- **Globalization:** With a presence in more than 150 countries, the combined entity will be better able to serve global market needs. Medtronic and Covidien have combined revenues of \$13 billion from outside the U.S., of which \$3.7 billion comes

from emerging markets. Covidien's extensive capabilities in emerging market R&D and manufacturing, joined with Medtronic's demonstrated clinical expertise across a much broader product offering, significantly increases the number of attractive solutions the new company will be able to offer to governments and major providers globally.

- **Economic Value:** Medtronic has adopted an intense focus on aligning with its customers to create more value in healthcare systems around the world - in various delivery and payment systems - by combining products, services and insights into solutions aimed at expanding access and reducing healthcare costs. With Covidien, Medtronic will be able to provide a broader array of complementary therapies and solutions that can be packaged to drive more value and efficiency in healthcare systems. Both companies' deep relationships with healthcare system stakeholders will provide enormous ability to identify and create further value-based solutions.

U.S. Investment Commitment as a Result of Combination

The U.S. is home to the global medtech industry, one of the most innovative global industries centered in the U.S., and medical devices are among the most valuable U.S. exports. The combined company is strongly committed to the U.S. as a healthcare innovator, strategic business partner and employer of choice.

As a direct benefit of the company's new financial structure, Medtronic will commit to \$10 billion in technology investments over the next 10 years in areas such as early stage venture capital investments, acquisitions and R&D in the U.S., above and beyond Medtronic's and Covidien's existing plans.

"The medical technology industry is critical to the U.S. economy, and we will continue to invest and innovate and create well-paying jobs," said Mr. Ishrak. "Medtronic has consistently been the leading innovator and investor in U.S. medtech, and this combination will allow us to accelerate those investments. These investments ultimately produce new therapy and treatment options that improve or save lives for millions of people around the world."

Structure and Governance

After the completion of the transaction, the businesses of Medtronic and Covidien will be combined under a new entity to be called Medtronic plc. It will have its principal executive offices in Ireland, where Covidien's current headquarters resides and where both companies have a longstanding presence. Medtronic plc will be led by Mr. Ishrak, and will continue to have its operational headquarters in Minneapolis, where Medtronic currently employs more than 8,000 people.

Financial Highlights

Upon completion of the transaction, each outstanding ordinary share of Covidien will be converted into the right to receive \$35.19 in cash and 0.956 of an ordinary share of Medtronic plc. The per-share consideration represents a premium of 29% to Covidien's closing stock price on June 13, 2014, the last trading day prior to the announcement. Medtronic shareholders will exchange each share of stock they own in Medtronic for one ordinary share of stock in Medtronic plc. The transaction is expected to be taxable, for U.S. federal income tax purposes, to shareholders of both Medtronic and Covidien.

The proposed transaction represents compelling value to Covidien shareholders through the cash component and continued participation in the future growth prospects expected to result from the combination through their ownership of approximately 30% of the combined company.

The transaction is expected to be accretive to Medtronic's cash earnings in FY 2016, the first full fiscal year, and significantly accretive thereafter. The transaction is also expected to be accretive to GAAP earnings by FY 2018.^[1]

The combination is expected to result in at least \$850 million of annual pre-tax cost synergies by the end of fiscal year 2018. These synergies include the benefits of optimizing global back-office, manufacturing and supply-chain infrastructure, as well as the elimination of redundant public company costs. The estimate excludes any benefit from potential revenue synergies resulting from the combination of the two organizations.

Through this combination, Medtronic is expected to generate significant free cash flow, which it will be able to deploy with greater strategic flexibility, particularly in the U.S.

The consummation of the transaction is subject to certain conditions, including approvals by Medtronic and Covidien

shareholders. In addition, the proposed transaction requires regulatory clearances in the U.S., the E.U., China and certain other countries. The transaction is expected to close in the fourth calendar quarter of 2014 or early 2015.

Medtronic's financial advisor is Perella Weinberg Partners LP and its legal advisors are Cleary Gottlieb Steen & Hamilton LLP and A & L Goodbody. Covidien's financial advisor is Goldman, Sachs & Co. and its legal advisors are Wachtell, Lipton, Rosen & Katz and Arthur Cox.

Bank of America Merrill Lynch provided committed financing for the transaction.

For more information about the transaction, please go to www.globalmedtechleader.com.

The announcement required under the Irish Takeover Rules (a Rule 2.5 announcement) has been made and is available at the above-listed website and at www.medtronic.com

Boilerplate omitted



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Puts Conditions on Medtronic's Proposed Acquisition of Covidien

Settlement Preserves Future Competition in Market for Certain Drug-coated Balloon Catheters

FOR RELEASE

November 26, 2014

TAGS: [Health Care](#) | [Medical Equipment and Devices](#) | [Bureau of Competition](#) | [Competition](#) | [Merger](#)

Global medical technology company [Medtronic, Inc.](#) has agreed to [divest the drug-coated balloon catheter business](#) of Ireland-based medical products company Covidien plc, in order to settle Federal Trade Commission charges that its \$42.9 billion acquisition of Covidien would likely be anticompetitive. Under the FTC's proposed settlement, Medtronic will sell the drug-coated balloon catheter business to a Colorado-based medical device company, The Spectranetics Corporation.

According to the FTC's [complaint both Medtronic and Covidien are developing drug-coated balloon catheters](#) to compete with C.R. Bard, Inc., which currently is the only company that supplies these products, used to treat peripheral artery disease, in the U.S. market. Medtronic and Covidien are the only companies with products in clinical trials in the Food and Drug Administration's approval process, which makes it unlikely that other competitors could enter the market in time to counteract the effects of the merger, the FTC alleges.

Under the proposed consent order, an interim monitor will supervise Medtronic and Covidien to oversee the transfer of rights and assets related to Covidien's drug-coated balloon catheter business to Spectranetics. According to the FTC's [analysis to aid public comment](#), Spectranetics currently manufactures and markets a range of devices to treat peripheral and coronary arterial disease, and has the industry and regulatory experience to obtain FDA approval for the product to enter the U.S. market as a viable competitor.

The proposed transaction was reviewed by antitrust enforcement agencies around the world, as well as by the Commission. FTC staff cooperated closely with antitrust agencies in Canada, China, the European Union, Japan, and Mexico.

The Commission vote to accept the proposed consent order for public comment was 5-0. The proposed settlement is part of the Commission's ongoing effort to protect U.S. consumers from higher healthcare-related costs.

The FTC will publish the consent agreement package in the Federal Register shortly. The agreement will be subject to public comment for 30 days, beginning today and continuing through December 29, 2014, after which the Commission will decide whether to make the proposed consent order final. Interested parties can [submit comments electronically](#).

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. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to \$16,000 per day.

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 Approves Final Order Preserving Future Competition in the Market for Drug-coated Balloon Catheters Used to Treat Peripheral Artery Disease](#)

Contact Information

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Betsy Lordan
Office of Public Affairs
202-326-3707

STAFF CONTACT:

Christine E. Tasso
Bureau of Competition
202-326-2232



ftc.gov

	)	
In the Matter of	)	
	)	
MEDTRONIC, INC.,	)	
a corporation;	)	
	)	Docket C-4503
and	)	
	)	
COVIDIEN PLC,	)	
a public limited company.	)	
<hr/>	)	

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Medtronic, Inc. (“Medtronic”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Covidien plc (“Covidien”), a public limited company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

1. Respondent Medtronic is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its headquarters address located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604.

2. Respondent Covidien is a public limited company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its headquarters address located at 20 on Hatch, Lower Hatch Street, Dublin 2, Ireland.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Pursuant to a Transaction Agreement dated June 15, 2014, Medtronic proposes to merge with Covidien in exchange for cash and stock valued at approximately \$42.9 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKET

5. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the development, licensing, manufacturing, marketing, distribution, and sale of drug-coated balloon catheters indicated for the femoropopliteal (“fem-pop”) artery.

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant line of commerce.

IV. THE STRUCTURE OF THE MARKET

7. Drug-coated balloon catheters indicated for the fem-pop artery are used to treat peripheral arterial disease in the fem-pop artery, an artery located above the knee. Peripheral arterial disease results from atherosclerosis, the narrowing of blood vessels due to plaque buildup. The U.S. market for drug-coated balloon catheters indicated for the fem-pop artery is highly concentrated with only one current supplier, C.R. Bard, Inc. Medtronic and Covidien are likely to enter as the second and third U.S. suppliers, respectively. Medtronic and Covidien are the only two potential market participants that have advanced to the clinical-trial stage of the Food and Drug Administration (“FDA”) approval process for drug-coated balloon catheters indicated for the fem-pop artery.

V. ENTRY CONDITIONS

8. Entry into the relevant market described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the product development times and FDA approval requirements are lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

9. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating future competition between Medtronic and Covidien in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery;
- b. by increasing the likelihood that the combined entity would forego or delay the launch of one company's drug-coated balloon catheter indicated for the fem-pop artery;
- c. by increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional U.S. supplier of drug-coated balloon catheters indicated for the fem-pop artery; and
- d. by reducing research and development in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery.

VII. VIOLATIONS CHARGED

10. The Transaction Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirteenth day of January, 2015, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL:

interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2014–28605 Filed 12–4–14; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 141 0187]

Medtronic, Inc. and Covidien plc; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 29, 2014.

ADDRESSES: Interested parties may file a comment at <https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Medtronic and Covidien—Consent Agreement; File No. 141 0187” on your comment and file your comment online at <https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “Medtronic and Covidien—Consent Agreement; File No. 141 0187” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:

Christine E. Tasso, Bureau of Competition, (202–326–2232), 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and

FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 26, 2014), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 29, 2014. Write “Medtronic and Covidien—Consent Agreement; File No. 141 0187” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which . . . is privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR

4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/covidienmedtronicconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you file your comment on paper, write “Medtronic and Covidien—Consent Agreement; File No. 141 0187” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 29, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted from Medtronic, Inc. (“Medtronic”) and Covidien plc (“Covidien”), subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) designed to remedy the anticompetitive effects resulting from

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

Medtronic's proposed acquisition of Covidien. Under the terms of the proposed Decision and Order ("Order") contained in the Consent Agreement, the parties are required to divest Covidien's drug-coated balloon catheter business to The Spectranetics Corporation ("Spectranetics").

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

Pursuant to a Transaction Agreement dated June 15, 2014, Medtronic proposes to merge with Covidien in exchange for cash and stock valued at approximately \$42.9 billion (the "Proposed Acquisition"). The Commission's Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. market for drug-coated balloon catheters indicated for the femoropopliteal ("fem-pop") artery. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

The Parties

Headquartered in Minneapolis, Minnesota, Medtronic is a global leader in medical technology that develops, manufactures, and sells device-based medical therapies. Medtronic is developing a drug-coated balloon catheter indicated for the fem-pop artery that is currently in the Food and Drug Administration ("FDA") approval process.

Headquartered in Dublin, Ireland, Covidien develops, manufactures, and sells medical devices and medical supplies. Like Medtronic, Covidien has a drug-coated balloon catheter indicated for the fem-pop artery under development for which it is seeking FDA approval.

The Relevant Product and Market Structure

Drug-coated balloon catheters indicated for the fem-pop artery are used to treat peripheral arterial disease in the fem-pop artery, an artery located above the knee. Peripheral arterial disease results from atherosclerosis, the

narrowing of blood vessels due to plaque buildup. Percutaneous transluminal angioplasty ("PTA") balloon catheters are catheters with balloons that, once inserted into an artery, are expanded to push plaque against the artery's lumen wall to reopen blood flow. Drug-coated balloon catheters are a type of PTA balloon catheter that releases paclitaxel, a cell-proliferation inhibiting drug, into the artery wall during a medical procedure to prevent restenosis, or re-narrowing, of the artery.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Drug-coated balloon catheters are medical devices that are regulated by the FDA. As such, drug-coated balloon catheters sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

The U.S. market for drug-coated balloon catheters indicated for the fem-pop artery is highly concentrated with only one current supplier, C.R. Bard, Inc. Medtronic and Covidien are likely to enter as the second and third U.S. suppliers, respectively. While there are other firms with drug-coated balloon catheters in development for sale in the U.S. market, Medtronic and Covidien are the only two anticipated market participants that have advanced to the clinical-trial stage of the FDA approval process for drug-coated balloon catheters indicated for the fem-pop artery.

Entry

Entry into the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The development process for a drug-coated balloon catheter is difficult, time-consuming, and expensive. It can take tens of millions of dollars of research and development, significant further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

Effects of the Acquisition

The Proposed Acquisition would cause significant competitive harm to consumers in the U.S. market for drug-coated balloon catheters indicated for

the fem-pop artery. The merger would combine the second and third anticipated entrants into the market, likely prolonging a duopoly in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery. Because Medtronic and Covidien are the only two anticipated entrants that have advanced to the clinical trial stage of the FDA approval process, the consolidation of the two firms would deprive consumers of the benefits of a third competitive entrant into the market for a substantial period of time. As a result, the Proposed Acquisition likely would reduce the substantial additional price competition that would have resulted from an additional U.S. supplier of drug-coated balloon catheters indicated for the fem-pop artery. Further, the Proposed Acquisition likely would reduce innovation in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery.

The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by Medtronic's proposed acquisition of Covidien by requiring the parties divest to Spectranetics all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S. market for drug-coated balloon catheters indicated for the fem-pop artery.

Spectranetics possesses the industry and regulatory experience to achieve FDA approval of Covidien's drug-coated balloon catheter and become the third entrant into the U.S. market. Headquartered in Colorado Springs, Colorado, Spectranetics is a leader in peripheral vascular solutions with a portfolio of products that is highly complementary to Covidien's drug-coated balloon catheter. Spectranetics manufactures and markets a range of devices to treat peripheral and coronary arterial disease and is well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Spectranetics will receive all rights and assets related to Covidien's drug-coated balloon catheter products, including all of the intellectual property used in the drug-coated balloon catheter business. In addition, Spectranetics will take over the manufacturing facility where Covidien currently coats the PTA balloon catheters with paclitaxel. The Order further requires that Covidien provide Spectranetics with a worldwide license to produce the PTA balloon catheters incorporated into the drug-coated balloon catheters. In order to

ensure continuity of supply of a critical input, the Order requires that the parties supply Spectranetics with PTA balloon catheters for up to three years while Spectranetics transitions to independent manufacturing. This provision ensures that drug-coated balloon catheters will continue to be available for ongoing clinical trials while Spectranetics works to obtain FDA approval to manufacture the PTA balloon catheters independently.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Spectranetics to assist the company in establishing its manufacturing capabilities and securing all necessary FDA approvals. Further, the Order requires that the parties transfer all confidential business information to Spectranetics, as well as provide access to employees who possess or are able to identify such information. Spectranetics also will have the right to interview and offer employment to employees associated with Covidien's drug-coated balloon catheter business.

The parties must accomplish the divestiture no later than ten days after the consummation of the Proposed Acquisition. If the Commission determines that Spectranetics is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Medtronic and Covidien comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Spectranetics. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2014-28609 Filed 12-4-14; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6056-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2015

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a \$553.00 calendar year (CY) 2015 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2015 and on or before December 31, 2015.

DATES: This notice is effective on January 1, 2015.

FOR FURTHER INFORMATION: Frank Whelan, (410) 786-1302 for Medicare enrollment issues. Alvin Anderson, (410) 786-2188 for Medicaid and CHIP enrollment issues.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period titled "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers." This rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and CHIP provider enrollment processes. As provided in section 1866(j)(2)(C)(i) of the Social Security Act (as amended by section 6401 of the Affordable Care Act) and in 42 CFR 424.514, "institutional providers" that are initially enrolling in the Medicare, Medicaid, or CHIP program, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An "institutional provider" for purposes of Medicare is defined at § 424.502 as "(a)ny provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-

855B (not including physician and non-physician practitioner organizations), CMS-855S, or associated Internet-based PECOS enrollment application." As we explained in the February 2, 2011 final rule (76 FR 5914), in addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only, and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), psychiatric residential treatment facilities, and may include other institutional provider types designated by a state in accordance with their approved state plan.

As indicated in §§ 424.514 and 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS-855I.
- A prospective or revalidating Medicaid or CHIP provider—
 - ++ Who is an individual physician or non-physician practitioner; or
 - ++ That is enrolled in Title XVIII of the Act or another state's Title XIX or XXI plan and has paid the application fee to a Medicare contractor or another state.

II. Provisions of the Notice

A. CY 2014 Fee Amount

In the December 2, 2013 **Federal Register** (78 FR 72089), we published a notice announcing a fee amount for the period of January 1, 2014 through December 31, 2014 of \$542.00. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of the Act established a \$500 application fee for institutional providers in CY 2010.
- Consistent with section 1866(j)(2)(C)(i)(II) of the Act, § 424.514(d)(2) states that for CY 2011 and subsequent years, the preceding year's fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year.
- The CPI-U increase for CY 2011 was 1.0 percent, based on data obtained from the Bureau of Labor Statistics (BLS). This resulted in an application fee amount for CY 2011 of \$505 (or \$500 × 1.01).
- The CPI-U increase for the period of July 1, 2010 through June 30, 2011 was 3.54 percent, based on BLS data. This resulted in an application fee amount for CY 2012 of \$522.87 (or \$505 × 1.0354). In the aforementioned February 2, 2011 final rule, we stated

Medtronic Completes Acquisition of Covidien

January 26, 2015 4:00 PM CT



DUBLIN, Ireland - January 26, 2015 - Medtronic plc (NYSE: MDT), a global leader in medical technology, services and solutions, announced today that it has successfully completed the previously announced acquisition of Covidien plc (NYSE: COV). Under the terms of the acquisition agreement, Medtronic, Inc. and Covidien plc are now combined under Medtronic plc. Shares of Medtronic plc are expected to begin trading on the New York Stock Exchange (NYSE) under the symbol "MDT" on Tuesday, January 27, 2015.

"The culmination of this acquisition marks a significant milestone in our industry, creating a company uniquely positioned to alleviate pain, restore health and extend life for more patients around the world. We can now bring together the extensive and innovative capabilities of both Medtronic and Covidien with an underlying objective to solve healthcare's biggest challenge - expanding access and improving clinical outcomes, while lowering costs," said Omar Ishrak, chairman and CEO of Medtronic. "This is an exciting day for our employees as we officially join forces to pursue our shared commitment to addressing universal healthcare needs and accelerating Medtronic's three fundamental strategies of therapy innovation, globalization and economic value. We know that our combined businesses can have a real and meaningful impact on people's lives - helping to treat more people, in more ways and in more places around the world."

Covidien shares and Medtronic, Inc. shares ceased trading on the New York Stock Exchange at the close of business today. The cash-and-stock transaction is valued at approximately \$49.9 billion, based on Medtronic's closing stock price of \$75.59 per share on January 26, 2015. Under the terms of the transaction, each ordinary share of Covidien outstanding as of the closing has been converted into the right to receive \$35.19 in cash and 0.956 of an ordinary share of Medtronic plc. Each share of Medtronic, Inc. common stock outstanding as of the closing has been converted into the right to receive one ordinary share of Medtronic plc.

Medtronic's financial advisor is Perella Weinberg Partners LP and its legal advisors are Cleary Gottlieb Steen & Hamilton LLP and A&L Goodbody. Covidien's financial advisor is Goldman Sachs and its legal advisors are Wachtell, Lipton, Rosen & Katz and Arthur Cox. The closing of the transaction does not affect the results of Medtronic, Inc.'s fiscal third quarter, which ended last week on Friday, January 23, 2015. The company expects to provide a financial update on its fiscal third quarter earnings conference call on Tuesday, February 17, 2015. For more detailed information on anticipated Medtronic plc revenue reporting changes and combined historical financials, see [Medtronic plc Revenue Reporting Changes and Historical Financials](#).

Medtronic plc has its principal executive offices in Ireland, where both companies have a longstanding presence. The company's operational headquarters will continue to be based in Minneapolis. Medtronic has a comprehensive product portfolio, a diversified growth profile and broad geographic reach, with more than 85,000 employees in more than 160 countries.

For more information, please visit www.medtronic.com.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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Source: The Spectranetics Corporation
January 27, 2015 08:20 ET

Spectranetics Completes Acquisition of Stellarex(TM) Drug Coated Balloon Assets From Covidien

COLORADO SPRINGS, Colo., Jan. 27, 2015 (GLOBE NEWSWIRE) -- The Spectranetics Corporation (Nasdaq:[SPNC](#)) today announced it has completed the acquisition of Covidien's Stellarex™ drug coated balloon angioplasty (DCB) platform. The transaction closed after the acquisition of Covidien by Medtronic.

The Stellarex DCB platform received European CE mark approval in December 2014. Spectranetics launched the product in Europe today, with U.S. commercialization anticipated in the 2017 timeframe, following FDA approval.

"This transaction meaningfully enhances Spectranetics' portfolio," said Scott Drake, President and CEO, Spectranetics. "Stellarex is an ideal strategic fit, complementing our suite of highly differentiated cardiovascular clinical solutions designed to enable physicians to cross, prepare and treat the most complex vascular disease. We are excited to have the Stellarex team become part of SPNC. They are an incredible asset and we are proud to advance their work as we continue with the ILLUMENATE clinical trials and product launch."

About the Stellarex DCB Platform

The Stellarex DCB platform is designed to treat peripheral arterial disease. Stellarex uses EnduraCoat™ technology, a durable, uniform coating designed to prevent drug loss during transit and facilitate controlled, efficient drug delivery to the treatment site. The Stellarex DCB platform received CE mark to be marketed in the European Union in December 2014. It is not approved in the United States, and is currently limited to investigational use.

About ILLUMENATE First-in-Human (FIH) Study

Data from the ILLUMENATE FIH Study was reported at the EuroPCR Scientific Congress in May 2014. The ILLUMENATE FIH Study is a prospective, multi-center, single-arm study designed to assess the clinical performance of the Stellarex DCB. In the study, 58 superficial femoral and/or popliteal lesions (up to 15 cm in length) in 50 patients were pre-dilated with an uncoated angioplasty balloon, followed by treatment with the Stellarex DCB. Clinical events were adjudicated by independent angiographic and sonographic core laboratories. The study found the Stellarex DCB to be safe, with durable results to 12 months, including:

- Primary patency (defined as the treated artery remaining open without further treatment required or renewed blockage detected by ultrasound scanning) was 89.5 percent at 12 months.
- Freedom from clinically driven target lesion revascularization through 12-month follow-up was 87.9 percent.
- No amputations or cardiovascular deaths were reported.

About ILLUMENATE Clinical Trials

The Stellarex DCB platform is being studied in an active Investigational Device Exemption (IDE) trial in the United States and internationally. There are four active ILLUMENATE clinical trials in addition to the First-in-Human ILLUMENATE trial, described above:

- ILLUMENATE Pharmacokinetic Study – to evaluate the drug levels in the blood; 25 patients to be enrolled at up to two sites
- ILLUMENATE Pivotal Trial – randomized trial to support PMA in the United States; up to 360 patients to be enrolled at 45 sites
- ILLUMENATE European Randomized Trial – similar to the U.S. Pivotal Trial; up to 360 patients to be enrolled at 30 sites
- ILLUMENATE Global Registry – non-randomized; up to 500 patients to be enrolled at 65 sites

These five clinical trials will be used to evaluate the safety and effectiveness of the Stellarex DCB platform and support United States and Canada regulatory approval.

About Spectranetics

SPNC develops, manufactures, markets and distributes single-use medical devices used in minimally invasive procedures within the cardiovascular system. The Company's products are sold in over 65 countries and are used to treat arterial blockages in the heart and legs and in the removal of pacemaker and defibrillator leads.

The Company's Vascular Intervention (VI) products include a range of laser catheters for ablation of blockages in arteries above and below the knee as well as the AngioSculpt® scoring balloon used in both peripheral and coronary procedures. The Company also markets support catheters to facilitate crossing of peripheral and coronary arterial blockages, and retrograde access and guidewire retrieval devices used in the treatment of peripheral arterial blockages, including chronic total occlusions. The Company markets aspiration and cardiac laser catheters to treat blockages in the heart.

The Lead Management (LM) product line includes excimer laser sheaths, dilator sheaths, mechanical sheaths and accessories for the removal of pacemaker and defibrillator cardiac leads.

For more information, visit www.spectranetics.com.

Spectranetics' Cautionary Statement Regarding Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities

Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. You can identify these statements because they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "look forward," "strive," "project," "intend," "should," "plan," "believe," "hope," "enable," "potential," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, clinical trials, regulatory or competitive environments, our intellectual property and product development. These forward-looking statements include, but are not limited to, statements regarding our expectation of continued growth and strength and the reasons for that growth, growth rates, strength, and outlook including projected revenue, net loss and Adjusted EBITDA. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements and to note they speak only as of the date of this release. These risks and uncertainties may include financial results differing from guidance, inability to successfully integrate AngioScore and the Stellarex platform into our business, market acceptance of excimer laser atherectomy technology and our vascular intervention and lead removal products, market acceptance of drug coated balloon technology, increasing price and product competition, increased pressure on expense levels resulting from expanded sales, marketing, product development and clinical activities, uncertain success of our strategic direction, dependence on new product development, loss of key personnel, uncertain success of or delays in our clinical trials, adverse results in any ongoing legal proceeding, or any legal proceeding in which we may become involved, adverse impact to our business of the health care reform and related legislation or regulations, including changes in reimbursements, continued or worsening adverse conditions in the general domestic and global economic markets and continued volatility and disruption of the credit markets, which affects the ability of hospitals and other health care systems to obtain credit and may impede our access to capital, intellectual property claims of third parties, availability of inventory from suppliers, adverse outcome of FDA inspections, the receipt of FDA approval to market new products or applications and the timeliness of any approvals, market acceptance of new products or applications, product defects, ability to manufacture sufficient volumes to fulfill customer demand, availability of vendor-sourced components at reasonable prices, unexpected delays or costs associated with any planned improvements to our manufacturing processes, and share price volatility due to the initiation or cessation of coverage, or changes in ratings, by securities analysts. For a further list and description of such risks and uncertainties that could cause our actual results, performance or achievements to materially differ from any anticipated results, performance or achievements, please see our previously filed SEC reports, including those risks set forth in our 2013 Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. We disclaim any intention or obligation to update or revise any financial or other projections or other forward-looking statements, whether because of new information, future events or otherwise.

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Steris/Synergy Health

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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) 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.

Boilerplate omitted



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@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 Dismisses Complaint against Steris and Synergy](#)

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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.	)	<u>OPINION AND ORDER</u>
	)	
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

¹In 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

²Synergy 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 country, 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

³Citation 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

⁴Citation 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 (Tyrański); 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

⁵Since 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

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

⁶The 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 Caribbean). (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

⁷Bouradel 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

⁸Not 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

⁹The 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



For Your Information

FTC Dismisses Complaint against Steris and Synergy

October 30, 2015



Tags: [Competition](#) | [Bureau of Competition](#) | [Merger](#) | [Health Care](#)

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 Federal Trade Commission works to [promote competition](#) and to protect and educate consumers. The FTC will never demand money, make threats, tell you to transfer money, or promise you a prize. You can learn more about [how competition benefits consumers](#) , [file an antitrust complaint](#), or [comment on a proposed merger](#). For the latest news and resources, [follow the FTC on social media](#), [subscribe to press releases](#) and [read our blog](#).

Press Release Reference

[FTC Challenges Merger of Companies That Provide Sterilization Services to Manufacturers](#)

Contact Information

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**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

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

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.