

HONORABLE SUZANNE R. PARIEN

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KING

STATE OF WASHINGTON,

Plaintiff,

Case No. 16-2-12186-1 SEA

CONSENT DECREE

v.

JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation, a wholly owned subsidiary of JOHNSON & JOHNSON; ETHICON US, LLC, a New Jersey Company, a wholly owned subsidiary of JOHNSON & JOHNSON; and DOES 1 through 100, inclusive,

Defendants.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

JUDGMENT SUMMARY

- | | | |
|----|---|--|
| 1. | Judgment Creditor | State of Washington |
| 2. | Judgment Debtor | Johnson & Johnson, Ethicon, Inc.,
and Ethicon US, LLC |
| 3. | Principal Judgment Amount | \$9,900,000 |
| 4. | Post Judgment Interest Rate
(from date Payment due in Para. 4.1) | 12 percent per annum |
| 5. | Attorneys for Judgment Creditor | Daniel L. Allen
Assistant Attorney General |
| 6. | Attorneys for Judgment Debtor | Stephen D. Brody
O'Melveny & Myers LLP
Angelo Calfo
Calfo Eakes & Ostrovsky PLLC
Carolyn Kubota
Covington & Burling LLP |

Plaintiff, the State of Washington, by and through the Attorney General, Robert W. Ferguson, has filed a Complaint for an injunction and other relief in this matter pursuant to RCW 19.86 (the "Washington Consumer Protection Act") alleging that Defendants Ethicon, Inc., and Ethicon US, LLC, and Johnson & Johnson (hereinafter "Defendants"), committed violations of the aforementioned Act. Plaintiff, by its counsel, and Defendants, by their counsel, have agreed to the entry of this Consent Decree by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

IT IS HEREBY ORDERED THAT:

I. FINDINGS

1.1 This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

1 1.2 The terms of this Consent Decree shall be governed by the laws of the State of
2 Washington.

3 1.3 Entry of this Consent Decree is in the public interest and reflects a negotiated
4 agreement among the Parties.

5 1.4 The Parties have agreed to resolve the issues resulting from the Covered Conduct
6 (defined below) by entering into this Consent Decree.

7 1.5 Defendants are willing to enter into this Consent Decree regarding the Covered
8 Conduct (defined below) in order to resolve the Attorney General's concerns under the
9 Washington Consumer Protection Act as to the matters addressed in this Consent Decree and
10 thereby avoid expense, inconvenience, and uncertainty.

11 1.6 Defendants are entering into this Consent Decree solely for the purpose of
12 settlement, and nothing contained herein may be taken as or construed to be an admission or
13 concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or
14 of any liability or wrongdoing, all of which Defendants expressly deny. Defendants do not admit
15 any violation of the Washington Consumer Protection Act (RCW 19.86), and do not admit any
16 wrongdoing that was or could have been alleged by any Attorney General before the date of the
17 Consent Decree under those laws. No part of this Consent Decree, including its statements and
18 commitments, shall constitute evidence of any liability, fault, or wrongdoing by Defendants.
19 This document and its contents are not intended for use by any third party for any purpose,
20 including submission to any court for any purpose.

21 1.7 This Consent Decree shall not be construed or used as a waiver or limitation of
22 any defense otherwise available to Defendants in any action, or of Defendants' right to defend
23 themselves from, or make any arguments in, any private individual, regulatory, governmental,
24 or class claims or suits relating to the subject matter or terms of this Consent Decree. This
25 Consent Decree is made without trial or adjudication of any issue of fact or law or finding of

1 liability of any kind. Notwithstanding the foregoing, Plaintiff may file an action to enforce the
2 terms of this Consent Decree.

3 1.8 It is the intent of the Parties that this Consent Decree not be admissible in other
4 cases or binding on Defendants in any respect other than in connection with the enforcement of
5 this Consent Decree.

6 1.9 No part of this Consent Decree shall create a private cause of action or confer any
7 right to any third party for violation of any federal or state statute, except that the State of
8 Washington may file an action to enforce the terms of this Consent Decree.

9 1.10 This Consent Decree (or any portion thereof) shall in no way be construed to
10 prohibit Defendants from making representations with respect to any Ethicon products that are
11 required under Federal law or regulations or in Food and Drug Administration ("FDA")
12 approved or cleared Labeling.

13 1.11 Nothing in this Consent Decree shall require Defendants to:

- 14 (a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21
15 U.S.C. § 301 *et seq.* ("FDCA") or any regulation promulgated thereunder,
16 or by the FDA; or
17 (b) fail to take any action that is required by the FDCA or any regulation
18 promulgated thereunder, or by the FDA.

19 II. DEFINITIONS

20 The following definitions shall be used in construing the Consent Decree:

21 2.1 "Covered Conduct" shall mean Defendants' marketing and promotional
22 practices, and dissemination of information to Health Care Providers (HCPs) and other
23 consumers, regarding Surgical Mesh products through the Effective Date of the Consent
24 Decree.

25 2.2 "Effective Date" shall mean the date on which a copy of the Consent Decree,

1 duly executed by Defendants and by Plaintiff, is approved by, and becomes a Consent Decree
2 of the Court.

3 2.3 "Health Care Provider" or "HCP" shall mean any physician or other health care
4 practitioner, who is licensed to provide health care services or to prescribe pharmaceutical
5 products and/or medical devices.

6 2.4 "Ethicon, Inc." shall mean Ethicon, Inc., and all of its predecessors,
7 subsidiaries, successors, and assigns, and each and all of its current and former officers,
8 directors, shareholders, employees, agents and representatives.

9 2.5 "Ethicon US, LLC" shall mean Ethicon US, LLC, and all of its predecessors,
10 subsidiaries, successors, and assigns, and each and all of its current and former officers,
11 directors, shareholders, employees, agents and representatives.

12 2.6 "Fair Balance" in the Promotion of Defendants' Surgical Mesh Devices shall
13 mean truthful, accurate, and presented in a balanced way, including an unbiased presentation of
14 scientific facts and data to achieve a balanced communication and shall require that should any
15 Promotional communication cite to a study or research Sponsored by Defendants that does not
16 disclose Defendants' Sponsorship, Defendants will make such disclosure in the Promotional
17 communication.

18 2.7 "Johnson & Johnson" shall mean Johnson & Johnson and all of its predecessors,
19 subsidiaries, successors, and assigns, and each and all of its current and former officers,
20 directors, shareholders, employees, agents and representatives.

21 2.8 "Parties" shall mean Ethicon, Inc., Ethicon US, LLC, Johnson & Johnson, and
22 Plaintiff, the State of Washington.

23 2.9 "Promotional," "Promoting," "Promote," or "Promoted" shall refer to any
24 representation about Defendants' Surgical Mesh devices intended to influence sales of that
25 product, including attempts to influence Health Care Professional practices for recommending

1 and/or patient consumers for utilizing that product, which would be deemed promotional labeling
2 or advertising under the FDCA or any regulation promulgated thereunder, or by the FDA, under
3 the most current draft or final standard promulgated by the FDA or the most current draft or final
4 FDA Guidance for Industry.

5 2.10 "Sponsored" and "Sponsorship" shall mean to pay or have paid in whole or in
6 part, to provide or have provided financial support or subsidization, or to provide or have
7 provided goods or materials of value in support of more than *de minimis* value.

8 2.11 "Surgical Mesh" shall mean any medical device (as the term "device" is defined
9 in 21 U.S.C. § 321(h)) that contains synthetic knitted mesh and that is intended to be
10 transvaginally-implanted in the pelvic floor to treat stress urinary incontinence (SUI) and/or
11 pelvic organ prolapse (POP).

12 2.12 Any reference to a written document shall mean a physical paper copy of the
13 document, electronic version of the document, or electronic access to such document.

14 III. COMPLIANCE PROVISION

15 3.1 Defendants shall not make, or cause to be made, in Promotional
16 communications or in material accompanying one of their Surgical Mesh devices, any written
17 or oral claim regarding Surgical Mesh that is deceptive or unfair, including any deceptive or
18 unfair communication of risk information, in violation of RCW 19.86, and all such
19 Promotional materials for Defendants' Surgical Mesh devices shall present a Fair Balance of
20 available information with respect to safety, efficacy, risks and complications of Defendants'
21 Surgical Mesh devices. To the extent Defendants learn of any new, clinically significant risks
22 associated with their Surgical Mesh devices that are not already disclosed in the current
23 versions of the devices' Instructions-for-Use, Defendants will update the risk information in
24 Promotional communications and in material accompanying their Surgical Mesh devices.
25

1 Investigative Demand (“CID”) or investigative subpoena authority, to the extent such authority
2 exists under applicable law, and Defendants reserve all of their rights in responding to a CID or
3 investigative subpoena issued pursuant to such authority.

4 5.2 Upon giving Defendants thirty (30) days to respond to the notification described
5 above, Plaintiff shall also be permitted reasonable access to inspect and copy relevant, non-
6 privileged, non-work product records and documents in the possession, custody, or control of
7 Defendants that relate to Defendants’ compliance with each provision of this Consent Decree
8 pursuant to that State’s CID or investigative subpoena authority. If Plaintiff makes or requests
9 copies of any documents during the course of that inspection, Plaintiff will provide a list of those
10 documents to Defendants.

11 5.3 Plaintiff may assert any claim that Defendants have violated this Consent Decree
12 in a separate civil action to enforce compliance with this Consent Decree, or may seek any other
13 relief afforded by law for violations of the Consent Decree, but only after providing Defendants
14 an opportunity to respond to the notification described in paragraph 5.1 above; provided,
15 however, that Plaintiff may take any action if Plaintiff believes that, because of the specific
16 practice, a threat to the health or safety of the public requires immediate action.

17 VI. RELEASE

18 6.1 Released Claims. By its execution of this Consent Decree, Plaintiff, the State of
19 Washington, releases and forever discharges Ethicon, Inc., Ethicon US, LLC, Johnson &
20 Johnson, and their past and present officers, directors, shareholders, employees, representatives,
21 agents, affiliates, parents, subsidiaries, predecessors, attorneys, assigns and successors
22 (collectively, the “Releasees”) from the following: all civil causes of action, claims, damages,
23 restitution, disgorgement, fines, costs, attorney’s fees, remedies and/or penalties that Plaintiff
24 has asserted or could have asserted against the Releasees under the Washington Consumer
25 Protection Act resulting from the Covered Conduct up to and including the Effective Date.

1 6.2 Claims Not Covered. Notwithstanding any term of this Consent Decree,
2 specifically reserved and excluded from the release in Paragraph 6.1 as to any entity or person,
3 including Releasees, are any and all of the following:

4 (a) Any criminal liability that any person or entity, including Releasees, has or may
5 have to the State of Washington;

6 (b) Any civil or administrative liability that any person and/or entity, including
7 Releasees, has or may have to the State of Washington not expressly covered by the
8 release in Subsection 6.1, including, but not limited to, any and all of the following
9 claims:

10 i. State or federal antitrust violations;

11 ii Claims involving “best price,” “average wholesale price,” “wholesale
12 acquisition cost,” or any reporting practices;

13 iii. Medicaid claims, including but not limited to federal Medicaid rebate
14 statute violations, Medicaid fraud or abuse (whether common law,
15 statutory or otherwise), and/or kickback violations related to the State of
16 Washington’s Medicaid program;

17 iv. State false claims violations; and

18 v. Claims to enforce the terms and conditions of this Consent Decree.

19 (c) Actions of, or on behalf of, state program payors of the State of Washington
20 arising from the purchase of Surgical Mesh.

21 (d) Any claims individual consumers have or may have under above-cited
22 Washington Consumer Protection Act, and any common law claims individual
23 consumers, including classes of consumers bringing class actions, may have concerning
24 unfair, fraudulent or deceptive trade practices against any person or entity, including the
25 Releasees.

1 7.4 The acceptance of this Consent Decree by the State of Washington shall not be
2 deemed approval by the State of Washington of any Defendant's advertising or business
3 practices. Further, neither Defendants nor anyone acting on their behalf shall state or imply, or
4 cause to be stated or implied, that the State of Washington or any of its governmental units has
5 approved, sanctioned or authorized any practice, act, advertisement, or conduct of Defendants.

6 7.5 Any failure by any party to this Consent Decree to insist upon the strict
7 performance by any other party of any of the provisions of this Consent Decree shall not be
8 deemed a waiver of any of the provisions of this Consent Decree, and such party,
9 notwithstanding such failure, shall have the right thereafter to insist upon the specific
10 performance of any and all of the provisions of this Consent Decree.

11 7.6 Duration. The term of this Consent Decree shall be five (5) years from its
12 Effective Date. Nothing in this Consent Decree shall relieve Defendants of their independent
13 obligation to fully comply with the laws of the State of Washington after the expiration of the
14 five-year term.

15 7.7 Entire Agreement: This Consent Decree represents the full and complete terms
16 of the settlement entered into by the Parties hereto. The Parties acknowledge that no other
17 promises, representations, or agreements of any nature have been made or entered into by the
18 Parties. The Parties further acknowledge that this Consent Decree constitutes a single and entire
19 agreement and is not severable or divisible, except that if any provision herein is found to be
20 legally insufficient or unenforceable, the remaining provisions shall continue in full force and
21 effect. In any action undertaken by the Parties, no prior versions of this Consent Decree and no
22 prior versions of any of its terms that were not entered by the Court in this Consent Decree may
23 be introduced for any purpose whatsoever.

24 7.8 Jurisdiction: This Court retains jurisdiction of this Consent Decree and the Parties
25 hereto for the purpose of enforcing and modifying this Consent Decree and for the purpose of

1 granting such additional relief as may be necessary and appropriate for the Duration of this
2 Consent Decree.

3 7.9 Counterparts: This Consent Decree may be executed in counterparts, and a
4 facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an
5 original signature.

6 7.10 Notice: All Notices under this Consent Decree shall be provided to the following
7 via email and Overnight Mail:

8 Defendants:

9 William Craco and Shelly Goldklang
10 Johnson & Johnson Law Department
11 One Johnson & Johnson Plaza
12 New Brunswick, NJ 08933
13 wcraco@its.jnj.com
14 sgoldkla@its.jnj.com

15 Copy to Johnson & Johnson's and Ethicon Inc.'s attorneys at
16 O'Melveny & Myers LLP, Calfo Eakes & Ostrovsky PLLC and Covington & Burling LLP via
17 electronic mail sent to:

18 Stephen Brody (sbrody@omm.com)
19 Angelo Calfo (angeloc@calfoeakes.com)
20 Carolyn Kubota (ckubota@cov.com)

21 Plaintiff:

22 Daniel L. Allen
23 Washington Assistant Attorney General
24 800 5th Avenue, Suite 2000
25 Seattle, Washington 98104
Telephone: 206-254-0575
Email: Daniel.Allen@atg.wa.gov

7.11 To the extent that any provision of this Consent Decree obligates Defendants to
change any policy(ies) or procedure(s) and to the extent not already accomplished, Defendants
shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later
than 120 days after the Effective Date of this Consent Decree.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this 22nd day of April, 2019.



Judge Suzanne R. Parisien

Judge Suzanne Parisien

1 For Plaintiff, State of Washington

2 By:

3 ROBERT W. FERGUSON
4 Attorney General

5 Dated:

6 7-21-19

7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CONSENT DECREE - 14

~~DEFENDANTS' PRETRIAL PROPOSED~~
~~FINDINGS OF FACT AND CONCLUSIONS~~
~~OF LAW - 14~~

LAW OFFICES
CALFO EAKES & OSTROVSKY PLLC
1301 SECOND AVENUE, SUITE 2800
SEATTLE, WASHINGTON 98101-3808
TEL. (206) 407-2200 FAX, (206) 407-2224

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

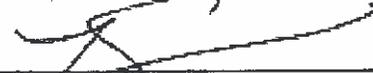
For Defendants

Johnson & Johnson

By: 
Tina French
Assistant Corporate Secretary

Dated: 4.19.19

Ethicon, Inc.

By: 
Tina French
Assistant Corporate Secretary

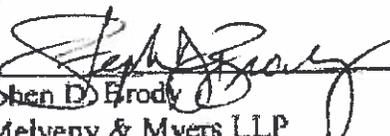
Dated: 4.19.19

Ethicon US, LLC

By: 
Tina French
Assistant Corporate Secretary

Dated: 4.19.19

Approved as to form:

By: 
Stephen D. Brody
O'Melveny & Myers LLP

Dated: 4/19/19