

EXHIBIT 1

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CLERK OF THE SUPERIOR COURT
By CHRISTNA ROGERS Deputy

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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA
UNLIMITED JURISDICTION

LHC GROUP, INC., Administrator of the
LHC Group Benefit Plan, on behalf of the Plan
and as subrogee,

Plaintiff,

vs.

BAYER CORP.;
BAYER HEALTHCARE LLC;
BAYER ESSURE INC. (F/K/A CONCEPTUS,
INC.);
BAYER HEALTHCARE
PHARMACEUTICALS, INC.; and
DOES 1 through 10, inclusive,

Defendant.

Case No.:

RG21094656

COMPLAINT FOR DAMAGES AND
DEMAND FOR JURY TRIAL

- (1) Negligence
- (2) Strict Products Liability
- (3) Concealment
- (4) Intentional Misrepresentation
- (5) Negligent Misrepresentation
- (6) Breach of Express Warranty
- (7) Quasi-Contract and Unjust Enrichment

COMES NOW Plaintiff LHC Group, Inc., Administrator of the LHC Group Benefit Plan (the "Plan"), on behalf of the Plan, and as subrogee of the Covered Persons and former Covered Persons ("Members") identified in Exhibit A (the "Injured Members"), and files this Complaint seeking judgment against Defendants BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Injured Members being implanted with the defective and unreasonably dangerous product, Essure®; for the cost of Plaintiff's purchase of such defective and unreasonably dangerous product on behalf of its Members; and for the cost incurred by Plaintiff to pay its Injured Members' healthcare costs when such costs should have been borne by Defendants. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

I. INTRODUCTION

1. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the U.S. Food and Drug Administration ("FDA"), and thereby to the healthcare community and to consumers. The manufacturer also must carefully monitor its own quality controls post-market to ensure that the device uniformly conforms with its representations and warranties and with specifications of approval.

3. When monitoring and reporting the post-market experience with its product, including any adverse events as required by both federal regulations and state law, including

1 California law, time is of the essence. The purpose of monitoring a product's post-market
2 experience is to detect potential safety signals that could indicate to the manufacturer and the
3 medical community that a public safety problem exists. If a manufacturer waits to report
4 post-market information, even for a few weeks or months, that bottleneck could mean that
5 researchers, regulatory bodies, and the medical community are years behind in identifying a
6 public safety issue associated with the device. In the meantime, more patients are harmed by
7 using the product without understanding its true risks. This is why a manufacturer must not
8 only completely and accurately monitor, investigate and report post-market experience, but
9 it must also report the data to the FDA as soon as it is received, take appropriate actions to
10 identify the root cause of product failures, and take corrective and preventative actions as
11 appropriate.

12 4. This action arises from Defendants' failure to uphold their post-market
13 responsibilities to warn about serious health risks that became apparent to the manufacturer
14 after their permanent birth control device, Essure®, was marketed in the United States. In
15 2002, the FDA approved the device for sale in the United States based on clinical studies of
16 only 745 women presented by the device manufacturer.

17 5. After the FDA approved the Essure device for sale and it began to be implanted in
18 patients in a real-world setting, Defendants became aware of serious issues and adverse
19 events that should have led Defendants to, among other things, report the adverse events to
20 the FDA pursuant to 21 C.F.R. § 803, et seq. For example, Defendants failed to disclose to
21 health care providers and consumers that they had received thousands of complaints of
22 serious injuries associated with Essure® after the device was approved for sale. The FDA
23 was not made aware that the device could cause serious health risks, such as perforation of
24 the uterus or fallopian tubes, device migration or fracture, chronic pain, prolonged bleeding,
25 and unintended pregnancies. The FDA was also not made aware that the frequency and
26 severity of complications was greater than expected, and ultimately the device must be
27 removed requiring major surgery.
28

6. Defendants failed to timely report this new information to the FDA. When the FDA later became aware of this information, it made Essure a restricted device and required additional warnings, including a black box warning and Patient Decision Checklist, to reflect serious health risks that were ultimately suffered by Injured Members. If the Defendants had timely and adequately disclosed this information and had reported serious adverse events to the FDA, Injured Members' injuries would have been avoided.

7. Despite their actual knowledge about the frequency, severity, and permanence of the clinical complications associated with Essure®, Defendants persisted in conducting a nationwide false and misleading marketing campaign. In Defendants' own words, their marketing strategy aimed to capitalize on a physician's position of trust with patients.

8. The conduct of Defendants violated their obligations under relevant federal and state law, including California law, governing the post-market conduct of Class III medical device manufacturers.

9. Plaintiff seeks relief only (1) as subrogee of its Injured Members for medical expenses actually paid, but not associated co-pays, co-insurance amounts or similar amounts expended by its Injured Members; (2) for damages it suffered directly, not as subrogee of its Members, and for which its Members have no claim; and (3) for punitive damages associated with these two types of claims only. Notwithstanding the foregoing allegations of this paragraph, or any other allegations of this Complaint, Plaintiff does not seek relief for damages that it cannot assert directly on its own behalf and to which it is not subrogated, or for which any of its Members are an indispensable party.

II. PARTIES, JURISDICTION AND VENUE

10. Plaintiff LHC Group, Inc. ("LHC Group") is a Delaware corporation with its principal corporate offices at 901 Hugh Wallis Road, South Lafayette, Louisiana 70508. LHC Group is the Administrator of the LHC Group Benefit Plan (the "Plan"), a copy of which is attached hereto as Exhibit B. LHC Group brings this action as Administrator of the Plan, both directly and as subrogee of Injured Member's claims against Defendants pursuant to Section 11.03 of the Plan.

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