OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

CIVIL INVESTIGATIVE DEMAND

TO: AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064

via CMRRR:
via First Class Mail
Return Date: April 14, 2022

Laura J. Schumacher
Vice Chairman, External Affairs and Chief Legal Officer

via Email: laura.schumacher@abbvie.com

Pursuant to this office's specific authority under section 17.61 of the Texas Deceptive Trade Practices—Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41–17.63 ("DTPA"), AbbVie Inc. is hereby directed to produce the items listed in Exhibit "A" attached hereto. Such production is governed by the instructions and definitions on this page and subsequent pages.

You are to make available the documentary material described in Exhibit "A" to the undersigned Assistant Attorney General or other authorized agent(s) identified by the Consumer Protection Division ("Division"). This documentary material shall be produced for inspection and copying during normal business hours at your principal office or place of business or may be sent electronically or by certified mail to the Office of Attorney General, 300 W. 15th Street, 9th Floor, Austin, TX 78701 and is due on April 14, 2022. If providing documents electronically, please provide them to Steven Robinson by email Steven.Robinson@oag.texas.gov. **Please contact me upon receipt in order to discuss the return date and the logistics of producing the requested documents to the Consumer Protection Division.**

The Division believes that you are in possession, custody, or control of documentary material relevant to the subject matter of an investigation of actual or possible violations of the DTPA sections 17.46(a) and 17.46(b) related to the advertising, marketing, promotion, sale and distribution of prescription hormone blockers for off-label usage.

TAKE NOTICE THAT pursuant to section 17.62, Texas Business and Commerce Code, any person who attempts to avoid, evade, or prevent compliance, in whole or in part, with this directive by removing, concealing, withholding, destroying, mutilating, altering, or by any other means falsifying any documentary material may be guilty of a misdemeanor and on conviction is punishable by a fine of not more than $5,000.00 or by confinement in the county jail for not more than one year, or both.

ISSUED THIS 24th day of March, 2022.

/s/ Steven Robinson
Steven Robinson
Chief, Consumer Protection
T: (512) 463-2185 | F: (512) 473-8301
Email: steven.robinson@oag.texas.gov

Instructions

1. **Read These Instructions/Definitions Carefully.** Your production must comply with these instructions and definitions.

2. **Duty to Preserve Documents**. All documents and/or other data which relate to the subject matter or requests of this Civil Investigative Demand must be preserved. ***Any ongoing, scheduled or other process of document or data destruction involving such documents or data must cease even if it is your normal or routine course of business for you to delete or destroy such documents or data and even if you believe such documents or data are protected from discovery by privilege or otherwise.*** Failure to preserve such documents or data may result in legal action and may be regarded as spoliation of evidence under applicable law.

3. **Relevant Dates**. Unless otherwise noted, the requests in this Civil Investigative Demand require production of documents from January 1, 2019, to the date of delivery of this Civil Investigative Demand, herein called "the relevant time period."

4. **Custody and Control.** In responding to this Civil Investigative Demand, you are required to produce not only all requested documents in your physical possession, but also all requested documents within your custody and control. A document is in your custody and control if it is the possession of another person and you have a right to possess that document that is equal or superior to that other person's right of possession. On the rare occasion that you cannot obtain the document, you must provide an explanation as to why you cannot obtain the document which includes the following information:

   a. The name of each author, sender, creator, and initiator of such document;

   b. the name of each recipient, addressee, or party for whom such document was intended;

   c. the date the document was created;

   d. the date(s) the document was in use;

   e. a detailed description of the content of the document;

   f. the reason it is no longer in your possession, custody or control; and

   g. the document's present whereabouts.

   If the document is no longer in existence, in addition to providing the information indicated above, state on whose instructions the document was destroyed or otherwise disposed of, and the date and manner of the destruction or disposal.

5. **Non-identical Copies to be Produced.** Any copy of a document that differs in any manner, including the presence of handwritten notations, different senders or recipients, etc. must be produced.

6. **No Redaction**. All materials or documents produced in response to this Civil Investigative Demand shall be produced in complete unabridged, unedited and unredacted form, even if portions may contain information not explicitly requested, or might include interim or final editions of a document.

7. **Document Organization**. Each document and other tangible thing produced shall be clearly designated as to which request, and each sub-part of a request, that it satisfies. The documents produced shall be identified and segregated to correspond with the number and subsection of the request.

8. **Production of Documents.** You may submit photocopies (with color photocopies where necessary to interpret the document) in lieu of original hard-copy documents if the photocopies provided are true, correct and complete copies of the original documents. If the requested information is electronically stored information, it shall be produced in electronic form. Electronically stored information shall be produced with the accompanying metadata, codes and programs necessary for translating it into usable form, or the information shall be produced in a finished usable form. For any questions related to the production of documents you may consult with the Office of the Attorney General representatives above.

Definitions

1. **"You," "your," "the business," "AbbVie"** means the entity named on page one of this Civil Investigative Demand and includes its past and present officers, employees, agents and representatives, parents and predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, and all persons and entities acting or purporting to act under the guidance or on behalf of any of the above. The terms "subsidiary," "affiliate," and "joint venture" refer to any firm in which there is total or partial ownership (25 percent or more) or control between the company and any other person or entity.

2. **"Advertisement"** means any act to bring to the public's attention the availability of goods and/or services and includes, but is not limited to, brochures, newspaper advertisements, yellow pages, internet, web or social media advertisements, websites, signs posted in or outside the business and radio or television advertisements.

3. "**Call notes**" means any document which contains a record of visits by your sales personnel to any health care provider, for the purpose of detailing hormone blockers or disseminating information about hormone blockers.

4. **"Communication"** is to be broadly construed and includes but is not limited to e-mails, notes, faxes, memos, text messages, social media posts, letters, notes of conversations and meetings and recordings of conversations and meetings, whether in text or audio form.

5. "**Concerning**" means directly or indirectly mentioning or describing, relating to, referring to, regarding, evidencing, setting forth, identifying, manifesting, memorializing, created in connection with or as a result of, commenting on, embodying, evaluating, analyzing, tracking, reflecting or constituting, in whole or in part, a stated subject matter.

6. "**Consumer**" means both individuals and businesses.

7. "**Detail**," "**detailing**," or "**detailed**" means any form of communication between your sales representatives or other employees and health care providers, including but not limited to, visits, telephone calls, voicemails, mail, group or individual emails, instant messages, social media

postings or messaging, and electronic message board posts.

8. **"Document"** means the original and all non-identical copies (whether different from the original because of notes, underlining, attachments, or otherwise) of all computer files, and all written, printed, graphic or recorded material of every kind, regardless of authorship. It includes communications in words, symbols, pictures, photographs, sounds, films, and tapes, as well as electronically stored information, computer files, together with all codes and/or programming instructions and other materials necessary to understand and use such systems.

9. "**Employee**" means and includes but is not limited to all current or former salaried employees, hourly employees, agents, independent contractors, individuals performing work as temporary employees, and staff of your board(s) of directors.

10. "**Health care provider**" and "**HCP**" means any physician, surgeon, nurse practitioner, physician assistant, physiatrist, psychiatrist, dentist, pharmacist, podiatrist, nurse, or other person engaged in the business of providing health care services and/or prescribing hormone blocker products in Texas, whether in Texas or another participating state, and any medical facility, hospital, or clinic, including but not limited to the current and former officers, directors, agents, representatives, or employees of any of the foregoing.

11. "**Identify**" or "**identity**" means the following:

a. When used in reference to a natural person, state (1) the person's full name; (2) the person's current or last known address; (3) the person's current or last known telephone number; (4) the person's current or last known email address; and (5) the person's occupation;

b. When used in reference to an artificial person or entity such as a corporation or partnership, state (1) the organization's full name and trade name, if any; (2) the address and telephone number of its principal place of business; and (3) the names and titles of the entity's officers, directors, and managing agents or employees;

c. When used in reference to a document, state (1) the type of document (*e.g.*, letter, memorandum, print-out, report, newspaper, etc.); (2) the title and date, if any, of the document; (3) all authors' names and addresses; (4) all addressees' names and addresses; (5) a brief description of the document's contents; (6) the present location of the document; and (7) the name and address of the person or persons having custody over the document. If any such document was, but is no longer, in your possession or custody or subject to your control, explain the disposition. In all cases where you are requested to identify particular documents, in lieu of such identification you may supply a fully legible exact copy of the document in question. Your acceptance of this option, however, shall in no way prejudice the State's right to require production and allow inspection of all records in your possession;

d. With respect to oral communications, set forth the following information: (1) the substance of the communication; (2) the date and time of the communication; (3) the place of origin of the communication; and if different, as in the case of telephone communications, the place at which the communication was received; (4) identification of each originator and recipient of the communication; and (5) identification of all

persons present at the place of origin, and if different, the place of receipt of the communication at the time the communication took place; and

e. When used in reference to a factual situation or allegation, state with particularity and specificity all facts known which bear upon or relate to the matter which is the subject of the inquiry, using the simplest and most factual statements of which you are capable.

12. **"Including"** means including, but not limited to.

13. "**Market**," "**marketing**," or "**marketed**" means all efforts and communication to promote or increase the use of hormone blockers generally or your hormone blocker products specifically, and includes branded and non-branded advertising and promotion in whatever form. It includes communications with and presentations relating to advisory groups.

14. "**Hormone blocker(s)**" or "**Puberty blocker(s)**" means medication(s) used to inhibit sex hormones, including but not limited to gonadotropin-releasing hormone (GnRH) agonists.

15. "**Person**" means any natural person or such person's legal representative; any partnership, domestic or foreign corporation, or limited liability company; any company, trust, business entity, association, or unincorporated association; and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, or trustee of another person.

16. **"Person"** includes you and means any entity or natural person.

17. "**Plans**" means documents or communications, including presentations, correspondence, or other memoranda setting forth ideas, thoughts, strategies, steps, formulas, or theories to promote your hormone blocker products or hormone blocker products generally. "Plans" means materials created by you as well as any third parties with whom you have contracted or communicated, and all drafts thereof.

18. "**Relating to**" or "**related to**" means, in whole or in part, constituting, concerning, evidencing, containing, discussing, commenting upon, describing, analyzing, identifying, stating, pertaining to, referring to, forming the basis of, in preparation of, or contradicting.

19. "**Sales personnel**" and "**sales representative**" mean any employee, agent, or independent contractor engaged in the sales, marketing, or promotion of your hormone blocker products or hormone blocker products generally.

EXHIBIT A: DOCUMENTS TO BE PRODUCED

1. Documents sufficient to identify all hormone blocker products that you sell, market, or distribute or have sold, marketed, or distributed from January 1, 2019, to the present, including:

   a. The brand name and generic name for each hormone blocker products;

   b. The brand name and generic name of each reformulation of such hormone blocker products, if any, and the date and purpose or nature of each reformulation;

   c. All available doses and forms of such hormone blocker products for each brand name and each reformulation;

   d. The National Drug Code packaging code(s) for each dose and form of each hormone blocker product; and

   e. The time period during which you sold, marketed, or promoted each hormone blocker product. If another company sold, marketed, or promoted the hormone blocker product before or after you did, please indicate the time period during which another company sold, marketed, or promoted the hormone blocker product.

2. Produce all documents related to the marketing and promotion of hormone blockers in Texas, including all branded and unbranded marketing materials, advertising, and educational materials, that contain information regarding the usage of hormone blockers, the potential for side effects for long-term usage of hormone blockers, and/or off-label uses of hormone blockers. The scope of this request includes, but is not limited to:

   a. Direct-to-consumer advertisements or other direct-to-consumer or patient communications;

   b. Advertisements or other marketing materials directed at HCPs;

   c. Slim Jims/pocket advertisements and similar materials;

   d. Leave behinds (including reprints);

   e. Posters;

   f. Brochures and pamphlets;

   g. Online and electronic materials provided to HCPs and patients/consumers, including emails, links to websites, and the name and address of each website where such materials appeared;

   h. Materials with your company's logo;

   i. Materials to be distributed by HCPs to patients/consumers; and

   j. Materials relating to the treatment of gender dysphoria, the prescribing of hormone-blocker-containing products, or hormone blockers generally that you provided to HCPs.

3. Provide all documents concerning all meetings, conversations, or other communications between you and HCPs in Texas during which your hormone blocker products, hormone blockers generally, and/or the use of hormone blockers for treatment of gender dysphoria was discussed, including but not limited to any call notes, or other notes, reports, analyses, or documents concerning such visits or communications.

4. Produce documents and communications related to materials provided to Texas health care providers describing off-label usage of hormone blockers. The scope of this request includes all communications from Texas health care providers requesting materials describing off-label usage of hormone blockers.

5. Provide all marketing and sales plans and communications relating to such plans, including all documents concerning competitive market share, growth plans, brand, and Strengths, Weaknesses, Opportunities, and Threats ("SWOT") analyses, for each hormone blocker product identified in Request 1, including projections and analyses prior to the U.S. Food and Drug Administration's ("FDA") approval (NDA, SNDA, or ANDA).

6. Provide all documents concerning the training or education of your sales representatives concerning your hormone blocker products, hormone blocker products by other manufacturers, or hormone blockers generally, including but not limited to employee handbooks, manuals, scripts, videos, agendas, talking points, presentations, memoranda, PowerPoint slides, recordings, email, and other messages. The scope of this request specifically includes training pertaining to off-label use of hormone blockers, including off-label use for treatment of gender dysphoria. For each document, state the time period for which it was effective.

7. Provide all documents concerning any internal communications, discussion, analyses, or deliberation within and among members of your risk management or similar committee(s) concerning the effectiveness of your hormone blocker products for treatment of gender dysphoria, hormone blocker use generally for treatment of gender dysphoria, and/or the risks associated with long-term hormone blocker use and/or hormone blocker use for treatment of gender dysphoria.

8. Produce any study or publication, including publication of a peer-reviewed article in any magazine or journal, that you sponsored or funded, in whole or in part, or to which you contributed in any way that relates to any of your hormone blocker products, hormone blockers generally, side effects of hormone blockers, or the treatment of gender dysphoria. In addition, provide the amount of each payment or contribution for each identified study or publication.

9. Provide all periodic reports or documents submitted to the FDA relating to your post-market surveillance requirements for each of your hormone blocker products identified in Request 1.

10. Provide all warning letters, untitled letters, advisory comments, or other communications from the FDA related to your marketing and advertising of your hormone blocker products.

11. Provide all communications, reports, analyses, and other documents concerning misuse, adverse events, side effects, and/or injury for your hormone blocker products. Include in your response: (a) all FDA MedWatch reports involving misuse, adverse events, side effects, and/or injury from your hormone blocker products; (b) all reports by sales representatives or others regarding misuse, adverse events, side effects, and/or injury; (c) all lists or databases you

maintained regarding misuse, adverse events, side effects, and/or injury; and (d) all communications with any professional, law enforcement, or government agencies, including federal, state, county, and municipal regulators, regarding misuse, adverse events, side effects, and/or injury.

12. Produce documents sufficient to identify all investigations of you by any law enforcement or government agencies, including federal, state, and municipal regulators, regarding marketing or representations made by you about the safety or effectiveness of your hormone blocker products or hormone blockers generally for the treatment of gender dysphoria.

13. Produce documents sufficient all lawsuits or private causes of action filed against you regarding marketing or representations made by you about the safety or effectiveness of your hormone blocker products or hormone blockers generally for the treatment of gender dysphoria.