OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

CIVIL INVESTIGATIVE DEMAND

TO: Moderna US, Inc.
200 Technology Square
Cambridge, Massachusetts
02139

via CMRRR: 7004 0750 0000 6764 1720
via First Class mail
Return Date: May 31, 2023

Registered Agent:
c/o CT Corporation System
1999 Bryan St., Ste. 900
Dallas, TX 75201

via CMRRR: 7004 0750 0000 6764 1737

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"), Moderna US, Inc., ("Moderna") 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 David Shatto, the undersigned Assistant Attorney General, or other authorized agent(s) identified by the Consumer Protection Division ("Division"). This documentary material is to be produced by **May 31, 2023** ("Return Date"). This documentary material may be sent by courier or certified mail to David Shatto at the Office of the Attorney General, Consumer Protection Division, PO Box 12548, Austin, Texas 78711-2548. If providing documents electronically, please provide them to Sam Weeks at Samuel.Weeks@oag.texas.gov.

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 DTPA sections 17.46(a), 17.46(b) and 17.46(c) with respect to false, misleading, and/or deceptive advertising regarding Moderna's Covid-19 Vaccine

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 1st day of May 2023.

David Shatto
Assistant Attorney General
T: (512) 463-2185 | F: (512) 370-9125
Email:david.shatto@oag.texas.gov

Other Authorized Agents:

Sam Weeks, Investigator
T: (512) 463-2185 | F: (512) 370-9125
Email: samuel.weeks@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, 2020, to the date of the production of documents in response to 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 in 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.

9. **Privilege Log.** For each Document and any other requested information that you assert is privileged or for any other reason excludable from production, please provide a privilege log, wherein you:

a. Identify that Document and other requested information;
b. State each specific ground for the claim of privilege or other ground for exclusion and the facts supporting each claim of privilege or other ground for exclusion;
c. State the date of the Document or other requested information; the name, job title, and address (including city, state, and ZIP Code) of the person who prepared it; the name, address (including city, state, and ZIP Code), and job title of the person to whom it was addressed or circulated or who saw it; and the name, job title, and address (including city, state, and ZIP Code) of the person now in possession of it; and
d. Describe the type and subject matter of the Document or other requested information.

Definitions

1. **"You," "Your," and/or "Moderna US, Inc.," (referred to herein as "Moderna")** means the entity named on page one of this Civil Investigative Demand and includes its past and present directors, 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 of 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 Moderna and any other Person or entity.

2. **"Advertisement"** or **"Advertising"** 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. The words **"and"** and **"or"** shall be construed either conjunctively or disjunctively as required by the context to bring within the scope of the request, any Document(s) that might be deemed outside its scope by another construction.

4. **"Call Notes"** means any Document which contains a record of visits by Your Sales Personnel to any Health Care Provider or Employee or federal, state, county, or municipal regulators, for the purpose of Detailing Covid-19 vaccine products or disseminating information about Covid-19 vaccine products.

5. **"CDC"** means the Centers for Disease Control and Prevention.

6. "**Communication**" means any conversation, discussion, letter, email, correspondence, memorandum, meeting, note, Call Note, analysis, deliberation, report, or other transmittal of information or message, whether transmitted in writing, orally, electronically, or by any other means.

7. "**Concerning,**" **"Relating To,"** or **"Related To"** means related to, referring to, pertaining to, concerning, describing, regarding, evidencing, or constituting.

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

9. **"Covid-19"** means the Coronavirus disease, and its variants, commonly called Covid-19.

10. **"Covid-19 Vaccine"** means a Moderna product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease or a preparation that is used to stimulate the body's immune response against diseases regarding the Coronavirus disease commonly called Covid-19, Including the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19).

11. **"Detailing"** means any form of Communication between Your Sales Representatives or other Employees and Health Care Provider or Employee or federal, state, county, or municipal regulators, 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.

12. "**Document**" is used herein in the broadest sense of the term and means all records and other tangible media of expression of whatever nature however and wherever created, produced, or stored (manually, mechanically, electronically, or otherwise), including without limitation all versions whether draft or final, all annotated or nonconforming or other copies, electronic mail (e-mail), instant messages, text messages or other wireless device messages, voicemail, calendars, date books, appointment books, diaries, books, papers, files, notes, confirmations, accounts statements, correspondence, memoranda, reports, records, journals, registers, analyses, plans, manuals, policies, telegrams, faxes, telexes, wires, telephone logs, telephone messages, message slips, minutes, notes or records or transcriptions of conversations or Communications or meetings, tape recordings, videotapes, disks, and other electronic media, microfilm, microfiche, storage devices, press releases, contracts, agreements, notices, and summaries. Any non-identical version of a document constitutes a separate document within this definition, Including without limitation drafts or copies bearing any notation, edit, comment, marginalia, underscoring, highlighting, marking, or any other alteration of any kind resulting in any difference between two or more otherwise identical documents. In the case of documents bearing any notation or other marking made by highlighting ink, the term document means the original version bearing the highlighting ink, which original must be produced as opposed to any copy thereof.

13. **"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.

14. **"FDA"** means the U.S. Food and Drug Administration.

15. **"Health Care Provider"** and **"HCP"** means any physician, surgeon, nurse practitioner, physician assistant, pharmacist, nurse, paramedic, or other Person engaged in the business of providing health care services and/or providing vaccinations to Consumers in Texas, whether in Texas or another participating state, and any medical facility, hospital, or clinic, Including the current and former officers, directors, agents, representatives, or Employees of any of the foregoing.

16. **"Identify"** 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 of its principal place of business; and (4) the names and titles of the entity's officers, directors, managing agents or Employees;
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.

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

18. **"Market," "Marketing," or "Marketed"** means all efforts and Communication to promote or increase the use of Vaccines for Covid-19 generally or Your Covid-19 Vaccine specifically, and branded and non-branded Advertising and promotion in whatever form. It includes Communications with and presentations Relating To advisory groups and media.

19. **"Person"** includes You and means any entity or natural person.

20. **"Plans"** means Documents or Communications, Including presentations, correspondence, or other memoranda setting forth ideas, thoughts, strategies, steps, formulas, or theories to promote Your Covid-19 Vaccine Including materials created by You as well as any third parties with whom You have contracted or communicated, and all drafts thereof.

21. **"Sales Personnel"** and **"Sales Representative"** mean any Employee, agent, or independent contractor engaged in the sales, Marketing, or promotion of Your Covid-19 Vaccine.

22. **"Vaccine"** means a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease or a preparation that is used to stimulate the body's immune response against diseases.

EXHIBIT A: DOCUMENTS TO BE PRODUCED

In accordance with the requirements set forth in the "Instructions" and "Definitions" sections of this Civil Investigative Demand, You are specifically required to respond in writing to each of the following Requests within the time frame set forth below:

Produce within 30 days:

1. Documents sufficient to Identify all Covid-19 Vaccines that You sell, Market, or distribute or have sold, Marketed, or distributed Including:

   a. The brand name and generic name for each Covid-19 Vaccine;
   b. The brand name and generic name of each reformulation of such Covid-19 Vaccine, if any, and the date and purpose or nature of each reformulation;
   c. All available doses and forms of such Covid-19 Vaccine for each brand name and each reformulation;
   d. The National Drug Code packaging code(s) for each dose and form of each Covid-19 Vaccine; and
   e. The time period during which You sold, Marketed, or promoted each Covid-19 Vaccine. If another company sold, Marketed, or promoted the Covid-19 Vaccine before or after You did, please indicate the time period during which another company sold, Marketed, or promoted the Covid-19 Vaccine.

2. Produce all Documents Related To the Marketing and promotion of Covid-19 Vaccines in Texas, Including all branded and unbranded Marketing materials, Advertising, educational materials, and supporting Documents, which contain information regarding the safety and effectiveness of Covid-19 Vaccines, and the potential for short and long-term side effects after a single dose or series of vaccinations.

3. Direct-to-consumer Advertisements or other direct-to-consumer or patient Communications Involving;

   a. Advertisements or other Marketing materials directed at HCP's.
   b. Slim Jims/pocket Advertisements and similar materials
   c. Leave behinds (Including reprints);
   d. Posters;
   e. Brochures and pamphlets;
   f. Online and electronic materials provided to HCP's and patients/Consumers, Including emails, links to websites, and the name and address of each website where such materials appeared;
   g. Materials with Your company's logo; and
   h. Materials to be distributed by HCP's to patients/Consumers.

4. Provide all Documents Concerning all meetings, conversations, or other Communications between You and HCP's in Texas during which Your Covid-19 Vaccine and/or the use of Vaccines to prevent or minimize the dangers of Covid-19 was discussed, Including any

Call Notes, or other notes, reports, analysis, or Documents Concerning such visits or Communications.

5. Provide all Marketing and sales Plans and Communications Relating To such Plans, Including all Documents Concerning competitive market share, growth Plans, and Strengths, Weaknesses, Opportunities, and Threats ("SWOT") analyses, for each Covid-19 Vaccine identified in Request 1, Including productions and analyses prior to the FDA Emergency Use Authorization.

6. Provide all Communications with any other manufacturer of Vaccines for Covid-19 that refer or relate to the sale or Marketing, or medical education Relating To, or grants to Vaccine advocacy organizations, or lobbying regarding access to Vaccines for Covid-19.

7. Provide all Documents regarding, and Communications with, any sales, marketing, advertising, or public relations agency or firm for the purpose of selling, Marketing, promoting, or Advertising Covid-19 Vaccines.

8. Provide Documents sufficient to Identify all domain names that You own(ed) and/or registered for websites created for patient or Consumer education or advocacy Concerning Your Covid-19 Vaccine or the prevention of disease through Vaccine administration.

9. Provide Documents sufficient to Identify, with service dates, Your Employees or consultants You utilize who serve or have served as members of, or on boards or committees of, or as consultants to, Vaccine advocacy organizations or other organizations or initiatives addressing disease prevention through Vaccines, Including any who have served in a governmental capacity, either federal, state, county, or municipal, that provides oversight to Moderna specifically and the biopharmaceutical industry generally.

10. Produce any study, publication, or research Document, 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 Covid-19 Vaccines, the prevention or reduction of Covid-19, and/or side effects of Vaccines for Covid-19 generally, with the supporting raw data.

11. Produce any study, publication, or research Document, Including publication of a peer-reviewed article in any magazine or journal, which is not included in Request 10, that relates to Your development of mRNA technology, Including any studies prior to the Relevant Dates. Produce the supporting raw data.

12. Provide a summary, and the raw data, of the Vaccines You currently produce, other than those identified in Request 10 or 11, and the rates of their adverse events, side effects, injuries and/or deaths for each Vaccine.

13. Provide all Communications within and among members of Your risk management or similar committee(s) Concerning the safety and effectiveness of Your Covid-19 Vaccine, Including short and long-term risks.

14. Provide all Communications within and among members of Your risk management or similar committee(s) Concerning the safety and effectiveness of Your mRNA technology, which are not included in Request 13, Including short and long-term risks. Include any prior to the Relevant Dates.

15. Provide all Communications, reports, analyses, and other Documents Concerning adverse events, side effects, injury and/or death for Your Covid-19 Vaccine. Include in Your response: (1) all FDA MedWatch reports involving adverse events, side effects, injuries and/or deaths from Your Covid-19 vaccine related product; (2) all reports by Sales Representatives or others regarding adverse events, side effects, injuries and/or deaths; (3) all lists or databases You maintained regarding adverse events, side effects, injuries and/or deaths; and (4) all Communications with any professional, law enforcement, or government agencies, Including federal, state, county, and municipal regulators, regarding adverse events, side effects, injuries and/or deaths.

16. Provide all periodic reports or Documents submitted to the FDA Relating To Your post-Market surveillance requirements for each of Your Covid-19 Vaccine products identified in Request 1.

17. Provide all warning letters, untitled letters, advisory comments, or other Communications from the FDA Related To Your Marketing and Advertising of Your Covid-19 Vaccine.

18. Produce Documents sufficient to determine if, and when, Moderna became aware of unexpected or additional adverse events, side effects, injuries and/or deaths Related To Your Covid-19 Vaccine after submitting Your original, and any subsequent, Covid-19 Vaccine label, and what those new risks were determined to be and their subsequent characterization.

19. Produce Documents sufficient to Identify all investigations of You by any law enforcement or government agencies, Including federal, state, county, and municipal regulators, regarding Marketing or representations made by You about the safety and effectiveness of Your Covid-19 Vaccine.

20. Produce Documents sufficient to Identify all investigations of You by any law enforcement or government agencies, Including federal, state, county, and municipal regulators, regarding Marketing or representations made by You about the transmissibility, or likelihood of transmitting Covid-19, after taking Your Covid-19 Vaccine.

21. Produce Documents sufficient to Identify all lawsuits or private causes of action filed against You regarding Marketing or representations made by You about the safety and effectiveness of Your Covid-19 Vaccine.

22. Produce Documents sufficient to Identify all lawsuits or private causes of action filed against You regarding Marketing or representations made by You about the transmissibility, or likelihood of transmitting Covid-19, after taking Your Covid-19 Vaccine.

23. Produce Communications and Documents sufficient to determine what statements the FDA approved Moderna to make Related To Covid-19 Vaccines and when the FDA approved those statements, Including each iteration of the FDA approved labeling, EUA fact sheets, Highlights of Prescribing Information, Full Prescribing information, HCP letters, and Patient fact sheets.

24. Produce Communications with the FDA Relating To the characterization of Covid-19 case confirmation, adverse events, side effects, injuries and/or deaths during the development of Your Covid-19 Vaccination specifically, or Your mRNA technology generally, Including any studies prior to the Relevant Dates.

25. Produce Communications and Documents sufficient to determine each iteration of Your Covid-19 Vaccine trial procedures, Including how and when to confirm COVID-19 through testing versus choosing not to test, and who has the authority to make those determinations.

26. Produce Documents sufficient to determine Your decision to use Relative Risk Reduction rather than Absolute Risk Reduction to characterize Your Covid-19 Vaccine efficacy rates.

27. Produce Communications with the CDC Related To the Vaccine definition change from "a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease" to "a preparation that is used to stimulate the body's immune response against diseases" on or around September 2021.

28. Produce all Communications and Documents Related To whistleblower reports or concerns regarding Your Covid-19 Vaccine trials or the safety or efficacy of Your Covid-19 Vaccine.

29. Produce all Communications and Documents Related To whistleblower reports or concerns regarding Your Covid-19 Vaccine trials or the transmissibility, or likelihood of transmitting Covid-19, after taking Your Covid-19 Vaccine.

30. Produce all Communications and Documents Related To any engagement in the study of Gain of Function or Directed Evolution in the study, analysis, trials, or preparation of the Covid-19 Vaccine.