

EXHIBIT D:
August 4, 2020 E-mail

Complaint for Injunctive Relief,
Reed Smith LLP v. Food & Drug Administration,
Civil Action No. 20-2786

Hussey, Emily L.

From: FDA_FOI@fda.gov
Sent: Tuesday, August 4, 2020 7:23 AM
To: Pontikes, Rachael G.
Subject: FDA Receipt of FOI Request

EXTERNAL E-MAIL - From FDA_FOI@fda.gov

Rachael Pontikes Rachael Pontikes

Re: Confirmation # FDA2067155
Requester Ctrl #:
In Reply refer to: 2020-5664

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

? All communications between FDA (including, but not limited to, FDA?s Center for Drug Evaluation and Research (?CDER?)) and the National Academies of Sciences, Engineering, and Medicine (including, but not limited to, Leigh Jackson), from January 1, 2016, to the present regarding the following subjects: o Bioidentical hormones; o Compounded bioidentical hormone therapy (otherwise known as ?cBHT? or ?cBHRT?); ETC

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see <http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Rochelle A. Coleman, Information Technician at 301-796-8982 or write to us at:

Division of Freedom of Information,
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Fax: 301-827-9267

You also have the right to seek dispute resolution services from:

FDA FOIA Public Liaison
Office of the Executive Secretariat
5630 Fishers Lane, Room 1050

Rockville, MD 20857
E-Mail: FDAFOIA@fda.hhs.gov

and/or:

Office of Government
Information Services
National Archives and Administration
8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-Mail: ogis@nara.gov
Fax: 202-741-5769

Note: Do NOT reply directly to this E-mail