

1 **MS. HOLMES' NOTICE**

2 On October 18, 2021, the government indicated that it will seek to introduce TX 167 into
3 evidence through the testimony of Dr. Shane Weber. TX 167 is an internal draft Pfizer document that
4 was never shared with Ms. Holmes or anyone else at Theranos. Ms. Holmes hereby notices her intent to
5 object to admission of that document under Rules 401, 402, 403, 702, 802, and 805, and this Court's
6 order requiring timely disclosure of expert witnesses. *See* Cline Decl. in Support of Ms. Holmes' Notice
7 ("Cline Decl."), Ex. 1 (TX 167).

8 **BACKGROUND**

9 Dr. Weber is a former Pfizer scientist who served during the relevant time as the Director of
10 Diagnostics in the company's Molecular Medicine Group. In December 2006, Theranos and Pfizer
11 contracted for Pfizer to conduct "an evaluation of Theranos technology to determine its application to
12 Pfizer's drug development efforts." TX 7753 at THER-0905833 (in evidence). The nearly two-year
13 project entailed assay development and validation by Theranos, Theranos' participation in a Pfizer-
14 sponsored clinical trial, and Theranos' compilation of a final report. *See id.* at THER-0905834, THER-
15 0905842-44. Theranos' participation in the study concluded in early October 2008, and Theranos
16 submitted the final report and associated assay data on October 11, 2008. Cline Decl., Ex. 2 (TX 143).

17 Dr. Weber was not involved in any of that work. As TX 167 notes, Theranos had multiple Pfizer
18 contacts since 2005—none of whom were Dr. Weber. Cline Decl., Ex. 1 at 3. Rather, Dr. Weber was
19 introduced to Theranos only in November 2008, after the work was completed. Over the subsequent six
20 weeks, he conducted a review comprised of what he described as "a one[-]hour teleconference" with
21 Theranos; review of the Theranos study report, publicly available patents, and Theranos' answers to 25
22 related follow-up questions; and conversations with unnamed Pfizer colleagues who, unlike Dr. Weber,
23 purported to have previously interacted with Theranos. *See generally id.* Following that review, Dr.
24 Weber drafted TX 167, a seven-page internal document dated December 31, 2008.

25 Dr. Weber's document states that its "purpose . . . was to close the loop on all previous efforts
26 for Theranos to look for business opportunities with Pfizer, and to make final recommendations
27 regarding potential future attempts for Theranos to engage different parts of Pfizer in their platforms."
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1 Cline Decl. Ex. 1 at 1. The document reflects Dr. Weber’s view that no such business opportunities
 2 existed, but that his group intended to “monitor[]” the Theranos-Pfizer relationship “[g]oing forward.”
 3 *Id.* The document does not purport to evaluate Theranos’ technology or the data generated in the
 4 Theranos-Pfizer clinical study. It does contain, however, inflammatory hearsay statements from Dr.
 5 Weber and others concerning their view of “Theranos” business marketing and the quality of its written
 6 deliverables. *See id.* at 1-2. Dr. Weber is likely to testify that he conveyed to Ms. Holmes by telephone
 7 that no immediate business opportunities existed at Pfizer for Theranos, but that he did not convey the
 8 internal document to anyone at Theranos.

9 MS. HOLMES’ OBJECTIONS

10 **Rules 401-402:** There is no evidence that Ms. Holmes was shown TX 167, or that it was
 11 transmitted to Theranos. As a result, this document is not probative of the allegation that Ms. Holmes
 12 “knew that these pharmaceutical companies and research institutions had not examined, used, or
 13 validated Theranos technology.” *See* Dkt. 469, ¶ 12(H). The Court has held that other evidence that is
 14 unconnected to Ms. Holmes is inadmissible, and should do the same here. *See, e.g.,* Dkt. 798 at 66-67
 15 (trade secrets); *id.* at 63-64 (alleged “bad acts” of certain Theranos employees).

16 **Rule 403:** Even if TX 167 has some minimal probative value, that value is far outweighed by the
 17 unfair prejudice associated with its admission. Again, Ms. Holmes did not receive, review, or endorse
 18 Dr. Weber’s document, and the document does not establish that Pfizer ultimately did not validate
 19 Theranos technology. Dkt. 469, ¶ 12(H).

20 On the other side of the ledger, TX 167 threatens to mislead the jury and inflict substantial unfair
 21 prejudice on Ms. Holmes. First, TX 167 is replete with language that—although bearing no relevance to
 22 the ultimate issues in the case—will have the effect of inflaming the jury and suggesting bad conduct on
 23 the part of unidentified individuals at “Theranos.” *See, e.g.,* Cline Decl. Ex. 1 at 1 (describing
 24 “Theranos” as “excessively pushy”); *id.* at 2 (characterizing the company’s “conclusions in their
 25 summary document” as “not believable”); *id.* (accusing “Theranos” of furnishing “non-informative,
 26 tangential, deflective or evasive answers to a written set of technical due diligence questions”).

27 Second, TX 167 makes sweeping statements about “Pfizer’s” course of dealing with Theranos—
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1 despite the fact that, by Dr. Weber’s own admission, TX 167 reflects his personal recommendations
2 based on his personal review and conversations with colleagues, not a memorialization of the reasons for
3 any final decision by Pfizer decisionmakers concerning the company’s relationship with Theranos. *See*
4 Ex. 3 at 2-3 (8/24/2021 MOI) (“[Dr. Weber] recognized the document as a summary of his position for
5 [three Pfizer executives]. . . . This was his final report and his conclusions never changed. . . . Weber
6 said the . . . ‘Recommendations’ were clear recommendations for review by directors and other company
7 vice presidents. . . . He did not know if anyone within Pfizer had overruled his recommendations . . .”).
8 These sweeping statements may mislead the jury to conclude that the document is a final formulation of
9 Pfizer’s position, when, in reality, it is nothing more than a summary of Dr. Weber’s personal
10 conclusions subject to revisiting.

11 Last, because the government has argued that Pfizer was “saying no” directly to Ms. Holmes,
12 9/8/2021 Gov’t Opening Statement Tr. 534:17-20, the jurors may wrongly assume that Ms. Holmes
13 received the document. Jurors may also wrongly interpret the document as bearing on the indictment
14 allegation—*i.e.*, as reflecting “Pfizer’s” view of Theranos’ technology performance (which it does not
15 do)—as opposed to reflecting the more limited (and less relevant) conclusion that, in Dr. Weber’s
16 opinion and in the opinion of the “two oncology Therapeutic Area Molecular Medicine Leads” to whom
17 he spoke, there were no apparent business opportunities for Theranos at Pfizer in December 2008. Cline
18 Decl. Ex. 1 at 1. These inferences would be contrary to the evidence.

19 **Rule 702, Dkt. 171:** TX 167 contains statements based on specialized knowledge that will
20 require explanation to lay jurors. *See, e.g.*, Ex. 1 at 2 (referencing “Sutent and other anti-EGFR receptor
21 or anti-angiogenesis therapies”); *id.* (discussing “working nucleic in vitro diagnostic assay platforms”
22 and “molecular test needs of the Pan Her and CDX-110 studies” and “Maraviroc tropism tests”). The
23 government has not disclosed Dr. Weber as an expert, contrary to the Court’s order requiring timely
24 disclosure of experts, Dkt. 171, and has given no indication of how it would satisfy the requirements of
25 Rule 702.¹

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27 ¹ Rule 702 applies even if the Court concludes that the document is a business record. *See Clark*
28 *v. City of Los Angeles*, 650 F.2d 1033, 1037 (9th Cir. 1981) (“Expressions of opinion or conclusions in a
business record are admissible only if the subject matter calls for an expert or professional opinion and
MS. HOLMES’ NOTICE OF OBJECTION TO TX 167
CR-18-00258 EJD

1 **Rules 802, 805:** Because there is no evidence that Ms. Holmes was shown TX 167, Ms. Holmes
2 presumes that the government seeks to introduce the document for the truth of the matter asserted. For
3 the reasons set forth below, the document is inadmissible as a business record. And even if the
4 document were a business record, it contains double hearsay from other Pfizer employees, and it is
5 unclear how the government could overcome the hearsay bar for those statements.

6 Numerous facts indicate that this document is not a “record[] of a regularly conducted activity.”
7 Fed. R. Evid. 803(6). First, Dr. Weber drafted TX 167 well after the events that the document purports
8 to assess—not “at or near the time” of those activities. Fed. R. Evid. 803(6)(A); *see Willco Kuwait*
9 *(Trading) S.A.K. v. deSavary*, 843 F.2d 618, 628 (1st Cir. 1988) (district court did not abuse discretion in
10 concluding that a telex was not a business record because, *inter alia*, the telex referred to an
11 “investigation and report which occurred more than three months before”); *United States v. Lemire*, 720
12 F.2d 1327, 1350 (D.C. Cir. 1983) (document summarizing background of dealings between two
13 counterparties, and explaining reasons for the award of a contract, was inadmissible as a business record,
14 because it recounted events that had occurred as long as one year and ten months before drafting).

15 Second, TX 167 bears the hallmarks of an ad-hoc document, not one “made pursuant to
16 established company procedures for the systematic or routine and timely making and preserving of
17 company records.” *Clark v. City of Los Angeles*, 650 F.2d 1033, 1037 (9th Cir. 1981). Dr. Weber’s
18 document is the product of a standalone, onetime review, rather than a routine, standardized, company
19 process. Documents created under such circumstances are not business records. *See* Fed. R. Evid. 803
20 Advisory Committee’s Note (“Absence of routineness raises lack of motivation to be accurate.”).

21 Third, the document is, on its face, a preliminary document. Although Dr. Weber’s prior
22 statement describes TX 167 as “his final report,” the document has all the indicia of a draft, not subject
23 to Fed. R. Evid. 803(6). Cline Decl. Ex. 3 at 2. The document contains typographical errors, bears a
24 stamp “Subject to Ongoing Management Review,” and, according to that prior statement, reflects only
25 Dr. Weber’s recommendation to his superiors at Pfizer. *Id.* at 2. For these reasons, TX 167 lacks the
26 reliability expected of documents subject to Fed. R. Evid. 803(6).

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28 is given by one with the required competence.”).

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/s/ John D. Cline
JOHN D. CLINE
Attorney for Elizabeth Holmes

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2021 a copy of this filing was delivered via ECF on all
counsel of record.

/s/ John D. Cline
JOHN D. CLINE
Attorney for Elizabeth Holmes

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