**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| **IN RE: ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION** | ) | **MDL NO.: 1:15-md-2657-FDS** |
| **This Document Relates to:** | ) | |
| **MDL Case No.:** | ) | |
| **Case Name:** | ) | |

## [JOINT PROPOSED] DEFENDANT FACT SHEET FOR GLAXOSMITHKLINE LLC

For each filed case from whom Defendant, GlaxoSmithKline LLC ("GSK"), has received a substantially complete and signed Plaintiff Fact Sheet ("PFS"), GSK must complete this Defendant Fact Sheet ("DFS") in accordance with the schedule established by the Court's Case Management Order. This DFS shall not preclude Plaintiffs from seeking additional documents and/or information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order(s).

In completing this DFS, GSK must make its best efforts to answer every question as specifically as possible. GSK will supplement its responses in accordance with the Federal Rules of Civil Procedure if it learns that they are incomplete or incorrect in any material respect.

GSK will attach additional sheets of paper if necessary and will identify any documents it is producing in response to a question or request herein by document number.

**[GSK's Proposal:** The section below proposed by Plaintiffs is not part of GSK's proposal.]

**[Plaintiffs' Proposal:** Each request not only calls for knowledge of GSK LLC, but also for the knowledge and documents that are available to GSK by reasonable inquiry including inquiry of GSK's parents, subsidiaries, predecessors, affiliates, divisions, officers, directors, employees, contractors and/or agents.]

## DEFINITIONS

As used herein, "YOU," "YOUR," or "YOURS" means GSK.

"DEFENDANT" shall refer to GSK.

"PLAINTIFF(S)" shall refer to the minor child who was exposed to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride *in utero* ("MINOR PLAINTIFF"); the woman who ingested Zofran®, Ondansetron, and/or Ondansetron Hydrochloride during the pregnancy with Minor Plaintiff ("MINOR PLAINTIFF'S MOTHER"); Minor Plaintiff's father; and/or Minor Plaintiff's parents/guardians.

As used herein, the phrase "TREATING HEALTHCARE PROVIDER" means: (1) any physician(s) or other individual medical provider(s) identified by full name and last known address in the PFS who prescribed and/or dispensed Zofran®, Ondansetron, and/or Ondansetron Hydrochloride to Minor Plaintiff's Mother during her pregnancy with Minor Plaintiff and (2) any physician, physician assistant, nurse practitioner, midwife, or other individual medical provider specializing in obstetrics or gynecology identified by full name and last known address in the PFS who treated Minor Plaintiff's Mother during the first trimester of her pregnancy with Minor Plaintiff.

As used herein, the term "DOCUMENT" shall, consistent with Fed. R. Civ. P. 34(a)(1)(A), refer to any "designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form."

## I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

## II. CONTACT WITH TREATING HEALTHCARE PROVIDERS

For each Treating Healthcare Provider, please provide the following:

A. Dear Doctor Letters: For each "Dear Doctor," "Dear Healthcare Professional," "Dear Colleague," as described in 21 CFR § 200.5, or other similar type of document that GSK sent to the Treating Healthcare Provider concerning Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify and produce the master letter sent, including document number.

**[GSK's Proposal:** The section below proposed by Plaintiffs is not part of GSK's proposal.**]**

**[Plaintiffs' Proposal:**

2. Identify and produce a redacted "list" reflecting the Treating Healthcare Providers(s) to whom the master letter was sent, including document number.**]**

3. State the date the master letter was sent to the Treating Healthcare Provider, the method of transmission, and provide the name and address to whom the letter was addressed.

4. Identify and produce any response received to any "Dear Doctor," "Dear Healthcare Professional, "Dear Colleague," or other similar type of document or letter.

| **Date Letter Sent and Method of Transmission** | **Document Number of Master Letter** | **Recipient (Name and Address)** |
|---|---|---|
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B. Medical Information Letters ("MIL"): If the Treating Healthcare Provider has ever initiated an information request to GSK related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify the date of the request, the method of transmission, and the name and address of the addressee.

2. Provide the name and address of the Treating Healthcare Provider who initiated the request.

3. Provide the document number or other identifying information of the request.

4. State whether or not a response to the request was sent or provided.

5. Produce a copy of any request identified in the chart below.

| Date of Request and Method of Transmission | Addressee (Name and Address) | Initiator (Name and Address) | Document Number of Request | Response (Yes/No) |
|---|---|---|---|---|
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C. In addition, for each information request to which an MIL or similar response was sent by GSK as indicated by a "Yes" above, please:

1. Identify the format of the MIL or response.

2. Identify the date the MIL or response was sent or provided and the method of transmission.

3. Provide the name and address of the sender of the MIL or response.

4. Provide the name and address of the addressee of the MIL or response.

5. Provide the document number of the MIL or response.

6. Produce a copy of any MIL or response indicated in the chart below.

| Format of MIL or Response | Date Sent and Method of Transmission | Sender (Name and Address) | Addressee (Name and Address) | Document Number of MIL or Response |
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D. Other Types of Contact: For each Treating Healthcare Provider, please:

**[GSK's Proposal:**

1. Identify by name all of the Sales Representatives, Territory Managers, District Managers, Sales Managers, Marketing Organization Representatives, medical liaisons, and/or any other detail persons compensated by GSK ("Representative") who came in contact with the

Treating Healthcare Provider(s) in connection with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride as a Representative for GSK, dates of employment, their last known address, and current title (or last known title if no longer employed by GSK).**]**

**[Plaintiffs' Proposal:**

1. Identify by name all of the Sales Representatives, Territory Managers, District Managers, Sales Managers, Marketing Organization Representatives, medical liaisons, and/or any other detail persons compensated by GSK ("Representative") who came in contact with the Treating Healthcare Provider(s) in connection with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride as a Representative for GSK, dates of employment, their last known address, **post graduate degree(s) received**, if any, and current title (or last known title if no longer employed by GSK).**]**

2. Produce "call notes" for each contact between the Treating Healthcare Provider and the Representative in a format to be agreed upon between the parties for any contact through the birth of Minor Plaintiff that relates to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and/or birth defects including the location where the contact occurred.

**[GSK's Proposal:** The section below proposed by Plaintiffs is not part of GSK's proposal**.]**

**[Plaintiffs' Proposal:**

In addition, state whether each Representative ever received a written reprimand by any person, entity, and/or government agency for his/her sales or marketing practices during the period of employment with GSK, acting as an agent or independent contractor on behalf of GSK.**]**

| **Healthcare Provider** | **Name of Representative and Last Known Address** | **Current or Former Employee and Dates of Employment** | **[Plaintiffs' Proposal: Education (Post Graduate Degree Received)]** | **Current Title or Last Title for Representative** | **[Plaintiffs' Proposal: Reprimand]** |
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E. Samples: If GSK or its Representative ever provided any Treating Healthcare Provider with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride samples, please provide the following:

1. Identify the Treating Healthcare Provider who received the samples.

2. Identify the date on which such samples were provided.

3. Identify the product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided to the Treating Healthcare Provider.

4. Identify the name of the Representative who provided the samples.

| **Healthcare Provider** | **Date Shipped/Provided** | **Product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided** | **Representative who Provided** |
|---|---|---|---|
| | | | |
| | | | |

## III. CONSULTING WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

**[GSK's Proposal:**

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, and/or compensated by GSK as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in a similar capacity **related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride** or otherwise has or had a financial relationship with GSK **related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride**, please:**]**

**[Plaintiffs' Proposal:**

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, and/or compensated by GSK as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical

investigator," "consultant," or in a similar capacity or otherwise has or had a financial relationship with GSK please:]

1. Identify the Treating Healthcare Provider.

2. Identify the date(s) that the Treating Healthcare Provider was consulted, retained, and/or compensated.

3. State the nature of the affiliation.

**[GSK's Proposal:**

4. State the amount of money, grant, or honorarium paid to the Treating Healthcare Provider.]

**[Plaintiffs' Proposal:**

4. State the amount of money, grant, or honorarium paid to the Treating Healthcare Provider(s) including 1099s reflecting payments or reimbursements of any nature to the Treating Healthcare Provider(s).]

| Treating Healthcare Provider | Date Consulted, Retained, or Compensated | Nature of Affiliation | Amount of Money, Grant, or Honorarium Paid |
|---|---|---|---|
| | | | |
| | | | |

B. For each Treating Healthcare Provider identified in response to III.A., please identify and produce all consulting agreements, contracts, and/or retainer agreements between the Treating Healthcare Provider and GSK.

Response:

_____

_____

## IV. OTHER CONTACT WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

A. Other contact with Plaintiff's Treating Healthcare Provider(s): To the extent it is referenced in a call note or through records of payments to Treating Healthcare Providers and identifiable, if the Treating Healthcare Provider has spoken at or attended any Continuing Medical Education courses (CMEs), conferences, lunches, dinners, movie nights, or other presentations sponsored in full or in part by GSK in which Zofran®, Ondansetron, and/or Ondansetron Hydrochloride was specifically discussed, please:

1. Identify the Treating Healthcare Provider.

2. Identify the date that the Treating Healthcare Provider attended and topic of said event.

3. State whether the Treating Healthcare Provider was a speaker or attendee.

| Treating Healthcare Provider | Date of Event | Speaker or Attendee |
|---|---|---|
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| | | |
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B. For any Treating Healthcare Provider identified in response to IV.A., please identify and produce all PowerPoints, documents, pamphlets, or correspondence used and/or provided at the event by GSK and/or any speaker(s) lecturing on behalf of GSK concerning the potential benefits, risks and/or warnings related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride use in pregnant women and/or morning sickness.

Response:

_____

_____

## V. PLAINTIFF'S TREATING HEALTHCARE PROVIDERS' PRACTICES

**[GSK's Proposal:**

For each Treating Healthcare Provider, please state whether you have in your possession prescriber-level information reflecting the Treating Healthcare Provider's prescriptions written for Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, including but not limited to the product(s) prescribed, the number of prescriptions, the number of refills, and the timeframe when these products were prescribed or refilled.**]**

**[Plaintiffs' Proposal:**

For each Treating Healthcare Provider, please state whether you have in your possession prescriber-level information reflecting the Treating Healthcare Provider's prescriptions written for Zofran®, Ondansetron, and/or Ondansetron Hydrochloride **or any other antiemetic,** including but not limited to the product(s) prescribed, the number of prescriptions, the number of refills, and the timeframe when these products were prescribed or refilled.**]**

Yes _____ No _____

If "Yes," please produce such documentation that may be permissibly provided under any applicable licensing agreements.

Response:

_____

_____

## VI. PLAINTIFF'S MEDICAL CONDITION

A. Other than in connection with any adverse event report, has GSK initiated contact with Plaintiff(s) or any of Plaintiffs' healthcare providers concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

_____

B. Other than in connection with any adverse event report, has GSK been contacted by Plaintiff(s), any of Plaintiffs' healthcare providers or anyone acting on Plaintiffs' behalf (other than Plaintiffs' counsel) concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or alleged injuries at issue in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

Response:

_____

_____

C. Please identify by document number and produce all non-privileged documents that reflect any communication between any person identified in Section VI.A. or VI.B. above and GSK concerning Plaintiffs.

Response:

_____

D. Please produce a copy of any Adverse Event Report or MedWatch form concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit as well as any underlying documentation, including, but not limited to, the adverse event source file, causality assessments, medical records, and non-privileged investigative reports that refers or relates to Plaintiff(s) or Minor Plaintiff.

Response:

_____

_____

E. Please identify by document number and produce any non-privileged surveillance, information, investigation, analysis, report, or any other internal information or documentation concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit

Response:

_____

_____

## CERTIFICATION OF COUNSEL

I, the undersigned counsel for GSK, certify under penalty of perjury that the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge, information, and belief and that I have engaged in best efforts to identify, locate, and supply all of the documents requested in this Defendant Fact Sheet.

Further, I acknowledge that I have an obligation to supplement the above responses, in accordance with the Federal Rules of Civil Procedure, if I learn that they are in some material respect incomplete or incorrect.

_____
Signature

_____
Printed Name

_____
Law Firm and Address

_____
Date

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

*/s/ Jennifer Hill*
Jennifer Hill

# Exhibit A

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| **IN RE: ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION** | ) | **MDL NO.: 1:15-md-2657-FDS** |
| **This Document Relates to:** | ) | |
| **MDL Case No.:** | ) | |
| **Case Name:** | ) | |

**[PLAINTIFFS' PROPOSED] DEFENDANT FACT SHEET FOR GLAXOSMITHKLINE LLC**

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In completing this DFS, GSK must make its best efforts to answer every question as specifically as possible. GSK will supplement its responses in accordance with the Federal Rules of Civil Procedure if it learns that they are incomplete or incorrect in any material respect.

GSK will attach additional sheets of paper if necessary and will identify any documents it is producing in response to a question or request herein by document number.

Each request not only calls for knowledge of GSK LLC, but also for the knowledge and documents that are available to GSK by reasonable inquiry including inquiry of GSK's parents, subsidiaries, predecessors, affiliates, divisions, officers, directors, employees, contractors and/or agents.

## DEFINITIONS

As used herein, "YOU," "YOUR," or "YOURS" means GSK.

"DEFENDANT" shall refer to GSK.

"PLAINTIFF(S)" shall refer to the minor child who was exposed to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride *in utero* ("MINOR PLAINTIFF"); the woman who ingested Zofran®, Ondansetron, and/or Ondansetron Hydrochloride during the pregnancy with Minor Plaintiff ("MINOR PLAINTIFF'S MOTHER"); Minor Plaintiff's father; and/or Minor Plaintiff's parents/guardians.

As used herein, the phrase "TREATING HEALTHCARE PROVIDER" means: (1) any physician(s) or other individual medical provider(s) identified by full name and last known address in the PFS who prescribed and/or dispensed Zofran®, Ondansetron, and/or Ondansetron Hydrochloride to Minor Plaintiff's Mother during her pregnancy with Minor Plaintiff and (2) any physician, physician assistant, nurse practitioner, midwife, or other individual medical provider specializing in obstetrics or gynecology identified by full name and last known address in the PFS who treated Minor Plaintiff's Mother during the first trimester of her pregnancy with Minor Plaintiff.

As used herein, the term "DOCUMENT" shall, consistent with Fed. R. Civ. P. 34(a)(1)(A), refer to any "designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form."

## I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

## II. CONTACT WITH TREATING HEALTHCARE PROVIDERS

For each Treating Healthcare Provider, please provide the following:

A. Dear Doctor Letters: For each "Dear Doctor," "Dear Healthcare Professional," "Dear Colleague," as described in 21 CFR § 200.5, or other similar type of document that GSK sent to the Treating Healthcare Provider concerning Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify and produce the master letter sent, including document number.

2. Identify and produce a redacted "list" reflecting the Treating Healthcare Providers(s) to whom the master letter was sent, including document number.

3. State the date the master letter was sent to the Treating Healthcare Provider, the method of transmission, and provide the name and address to whom the letter was addressed.

4. Identify and produce any response received to any "Dear Doctor," "Dear Healthcare Professional, "Dear Colleague," or other similar type of document or letter.

| **Date Letter Sent and Method of Transmission** | **Document Number of Master Letter** | **Recipient (Name and Address)** |
|---|---|---|
| | | |
| | | |
| | | |

B. Medical Information Letters ("MIL"): If the Treating Healthcare Provider has ever initiated an information request to GSK related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify the date of the request, the method of transmission, and the name and address of the addressee.

2. Provide the name and address of the Treating Healthcare Provider who initiated the request.

3. Provide the document number or other identifying information of the request.

4. State whether or not a response to the request was sent or provided.

5. Produce a copy of any request identified in the chart below.

| **Date of Request and Method of Transmission** | **Addressee (Name and Address)** | **Initiator (Name and Address)** | **Document Number of Request** | **Response (Yes/No)** |
|---|---|---|---|---|
| | | | | |
| | | | | |

C. In addition, for each information request to which an MIL or similar response was sent by GSK as indicated by a "Yes" above, please:

1. Identify the format of the MIL or response.

2. Identify the date the MIL or response was sent or provided and the method of transmission.

3. Provide the name and address of the sender of the MIL or response.

4. Provide the name and address of the addressee of the MIL or response.

5. Provide the document number of the MIL or response.

6. Produce a copy of any MIL or response indicated in the chart below.

| **Format of MIL or Response** | **Date Sent and Method of Transmission** | **Sender (Name and Address)** | **Addressee (Name and Address)** | **Document Number of MIL or Response** |
|---|---|---|---|---|
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| | | | | |
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D. Other Types of Contact: For each Treating Healthcare Provider, please:

1. Identify by name all of the Sales Representatives, Territory Managers, District Managers, Sales Managers, Marketing Organization Representatives, medical liaisons, and/or any other detail persons compensated by GSK ("Representative") who came in contact with the Treating Healthcare Provider(s) in connection with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride as a Representative for GSK, dates of employment, their last known address, post graduate degree(s) received, if any, and current title (or last known title if no longer employed by GSK).

2. Produce "call notes" for each contact between the Treating Healthcare Provider and the Representative in a format to be agreed upon between the parties for any contact through the birth of Minor Plaintiff that relates to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and/or birth defects including the location where the contact occurred.

In addition, state whether each Representative ever received a written reprimand by any person, entity, and/or government agency for his/her sales or marketing practices during the period of employment with GSK, acting as an agent or independent contractor on behalf of GSK.

| **Healthcare Provider** | **Name of Representative and Last Known Address** | **Current or Former Employee and Dates of Employment** | **Education (Post Graduate Degree Received)** | **Current Title or Last Title for Representative** | **Reprimand** |
|---|---|---|---|---|---|
| | | | | | |
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E. Samples: If GSK or its Representative ever provided any Treating Healthcare Provider with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride samples, please provide the following:

1. Identify the Treating Healthcare Provider who received the samples.

2. Identify the date on which such samples were provided.

3. Identify the product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided to the Treating Healthcare Provider.

4. Identify the name of the Representative who provided the samples.

| **Healthcare Provider** | **Date Shipped/Provided** | **Product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided** | **Representative who Provided** |
|---|---|---|---|
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## III. CONSULTING WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, and/or compensated by GSK as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in a similar capacity or otherwise has or had a financial relationship with GSK please:

1. Identify the Treating Healthcare Provider.

2. Identify the date(s) that the Treating Healthcare Provider was consulted, retained, and/or compensated.

3. State the nature of the affiliation.

4. State the amount of money, grant, or honorarium paid to the Treating Healthcare Provider(s) including 1099s reflecting payments or reimbursements of any nature to the Treating Healthcare Provider(s).

| **Treating Healthcare Provider** | **Date Consulted, Retained, or Compensated** | **Nature of Affiliation** | **Amount of Money, Grant, or Honorarium Paid** |
|---|---|---|---|
| | | | |
| | | | |

B. For each Treating Healthcare Provider identified in response to III.A., please identify and produce all consulting agreements, contracts, and/or retainer agreements between the Treating Healthcare Provider and GSK.

Response:

_____

_____

## IV. OTHER CONTACT WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

A. Other contact with Plaintiff's Treating Healthcare Provider(s): To the extent it is referenced in a call note or through records of payments to Treating Healthcare Providers and identifiable, if the Treating Healthcare Provider has spoken at or attended any Continuing Medical Education courses (CMEs), conferences, lunches, dinners, movie nights, or other presentations sponsored in full or in part by GSK in which Zofran®, Ondansetron, and/or Ondansetron Hydrochloride was specifically discussed, please:

1. Identify the Treating Healthcare Provider.

2. Identify the date that the Treating Healthcare Provider attended and topic of said event.

3. State whether the Treating Healthcare Provider was a speaker or attendee.

| Treating Healthcare Provider | Date of Event | Speaker or Attendee |
|---|---|---|
| | | |
| | | |
| | | |

B. For any Treating Healthcare Provider identified in response to IV.A., please identify and produce all PowerPoints, documents, pamphlets, or correspondence used and/or provided at the event by GSK and/or any speaker(s) lecturing on behalf of GSK concerning the potential benefits, risks and/or warnings related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride use in pregnant women and/or morning sickness.

Response:

_____

_____

## V. PLAINTIFF'S TREATING HEALTHCARE PROVIDERS' PRACTICES

For each Treating Healthcare Provider, please state whether you have in your possession prescriber-level information reflecting the Treating Healthcare Provider's prescriptions written for Zofran®, Ondansetron, and/or Ondansetron Hydrochloride or any other

antiemetic, including but not limited to the product(s) prescribed, the number of prescriptions, the number of refills, and the timeframe when these products were prescribed or refilled.

Yes _____ No _____

If "Yes," please produce such documentation that may be permissibly provided under any applicable licensing agreements.

Response:

_____

_____

## VI. PLAINTIFF'S MEDICAL CONDITION

A. Other than in connection with any adverse event report, has GSK initiated contact with Plaintiff(s) or any of Plaintiffs' healthcare providers concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

_____

B. Other than in connection with any adverse event report, has GSK been contacted by Plaintiff(s), any of Plaintiffs' healthcare providers or anyone acting on Plaintiffs' behalf (other than Plaintiffs' counsel) concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or alleged injuries at issue in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

Response:

_____

_____

C. Please identify by document number and produce all non-privileged documents that reflect any communication between any person identified in Section VI.A. or VI.B. above and GSK concerning Plaintiffs.

Response:

_____

_____

D. Please produce a copy of any Adverse Event Report or MedWatch form concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit as well as any underlying documentation, including, but not limited to, the adverse event source file, causality assessments, medical records, and non-privileged investigative reports that refers or relates to Plaintiff(s) or Minor Plaintiff.

Response:

_____

_____

E. Please identify by document number and produce any non-privileged surveillance, information, investigation, analysis, report, or any other internal information or documentation concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit

Response:

_____

_____

## CERTIFICATION OF COUNSEL

I, the undersigned counsel for GSK, certify under penalty of perjury that the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge, information, and belief and that I have engaged in best efforts to identify, locate, and supply all of the documents requested in this Defendant Fact Sheet.

Further, I acknowledge that I have an obligation to supplement the above responses, in accordance with the Federal Rules of Civil Procedure, if I learn that they are in some material respect incomplete or incorrect.

_____
Signature

_____
Printed Name

_____
Law Firm and Address

_____
Date

# Exhibit B

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| **IN RE: ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION** | ) | **MDL NO.: 1:15-md-2657-FDS** |
| **This Document Relates to:** | ) | |
| **MDL Case No.:** | ) | |
| **Case Name:** | ) | |

**[GLAXOSMITHKLINE LLC'S PROPOSED] DEFENDANT FACT SHEET FOR GLAXOSMITHKLINE LLC**

For each filed case from whom Defendant, GlaxoSmithKline LLC ("GSK"), has received a substantially complete and signed Plaintiff Fact Sheet ("PFS"), GSK must complete this Defendant Fact Sheet ("DFS") in accordance with the schedule established by the Court's Case Management Order. This DFS shall not preclude Plaintiffs from seeking additional documents and/or information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order(s).

In completing this DFS, GSK must make its best efforts to answer every question as specifically as possible. GSK will supplement its responses in accordance with the Federal Rules of Civil Procedure if it learns that they are incomplete or incorrect in any material respect.

GSK will attach additional sheets of paper if necessary and will identify any documents it is producing in response to a question or request herein by document number.

## DEFINITIONS

As used herein, "YOU," "YOUR," or "YOURS" means GSK.

"DEFENDANT" shall refer to GSK.

"PLAINTIFF(S)" shall refer to the minor child who was exposed to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride *in utero* ("MINOR PLAINTIFF"); the woman who ingested Zofran®, Ondansetron, and/or Ondansetron Hydrochloride during the pregnancy with Minor Plaintiff ("MINOR PLAINTIFF'S MOTHER"); Minor Plaintiff's father; and/or Minor Plaintiff's parents/guardians.

As used herein, the phrase "TREATING HEALTHCARE PROVIDER" means: (1) any physician(s) or other individual medical provider(s) identified by full name and last known address in the PFS who prescribed and/or dispensed Zofran®, Ondansetron, and/or Ondansetron Hydrochloride to Minor Plaintiff's Mother during her pregnancy with Minor Plaintiff and (2) any physician, physician assistant, nurse practitioner, midwife, or other individual medical provider specializing in obstetrics or gynecology identified by full name and last known address in the PFS who treated Minor Plaintiff's Mother during the first trimester of her pregnancy with Minor Plaintiff.

As used herein, the term "DOCUMENT" shall, consistent with Fed. R. Civ. P. 34(a)(1)(A), refer to any "designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form."

## I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

## II. CONTACT WITH TREATING HEALTHCARE PROVIDERS

For each Treating Healthcare Provider, please provide the following:

A. Dear Doctor Letters: For each "Dear Doctor," "Dear Healthcare Professional," "Dear Colleague," as described in 21 CFR § 200.5, or other similar type of document that GSK sent to the Treating Healthcare Provider concerning Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify and produce the master letter sent, including document number.

2. State the date the master letter was sent to the Treating Healthcare Provider, the method of transmission, and provide the name and address to whom the letter was addressed.

3. Identify and produce any response received to any "Dear Doctor," "Dear Healthcare Professional, "Dear Colleague," or other similar type of document or letter.

| **Date Letter Sent and Method of Transmission** | **Document Number of Master Letter** | **Recipient (Name and Address)** |
|---|---|---|
| | | |
| | | |
| | | |

B. Medical Information Letters ("MIL"): If the Treating Healthcare Provider has ever initiated an information request to GSK related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify the date of the request, the method of transmission, and the name and address of the addressee.

2. Provide the name and address of the Treating Healthcare Provider who initiated the request.

3. Provide the document number or other identifying information of the request.

4. State whether or not a response to the request was sent or provided.

5. Produce a copy of any request identified in the chart below.

| **Date of Request and Method of Transmission** | **Addressee (Name and Address)** | **Initiator (Name and Address)** | **Document Number of Request** | **Response (Yes/No)** |
|---|---|---|---|---|
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C. In addition, for each information request to which an MIL or similar response was

sent by GSK as indicated by a "Yes" above, please:

1. Identify the format of the MIL or response.

2. Identify the date the MIL or response was sent or provided and the method of transmission.

3. Provide the name and address of the sender of the MIL or response.

4. Provide the name and address of the addressee of the MIL or response.

5. Provide the document number of the MIL or response.

6. Produce a copy of any MIL or response indicated in the chart below.

| **Format of MIL or Response** | **Date Sent and Method of Transmission** | **Sender (Name and Address)** | **Addressee (Name and Address)** | **Document Number of MIL or Response** |
|---|---|---|---|---|
| | | | | |
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D. Other Types of Contact: For each Treating Healthcare Provider, please:

1. Identify by name all of the Sales Representatives, Territory Managers, District Managers, Sales Managers, Marketing Organization Representatives, medical liaisons, and/or any other detail persons compensated by GSK ("Representative") who came in contact with the Treating Healthcare Provider(s) in connection with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride as a Representative for GSK, dates of employment, their last known address, and current title (or last known title if no longer employed by GSK).

2. Produce "call notes" for each contact between the Treating Healthcare Provider and the Representative in a format to be agreed upon between the parties for any contact through the birth of Minor Plaintiff that relates to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and/or birth defects including the location where the contact occurred.

| Healthcare Provider | Name of Representative and Last Known Address | Current or Former Employee and Dates of Employment | Current Title or Last Title for Representative |
|---|---|---|---|
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E. Samples: If GSK or its Representative ever provided any Treating Healthcare Provider with Zofran®, Ondansetron, and/or Ondansetron Hydrochloride samples, please provide the following:

1. Identify the Treating Healthcare Provider who received the samples.

2. Identify the date on which such samples were provided.

3. Identify the product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided to the Treating Healthcare Provider.

4. Identify the name of the Representative who provided the samples.

| Healthcare Provider | Date Shipped/Provided | Product name, product formulation, dosage, number of doses contained in each sample, and the number of samples provided | Representative who Provided |
|---|---|---|---|
| | | | |
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## III. CONSULTING WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, and/or compensated by GSK as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in a similar capacity related to Zofran®,

Ondansetron, and/or Ondansetron Hydrochloride or otherwise has or had a financial relationship with GSK related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, please:

1. Identify the Treating Healthcare Provider.

2. Identify the date(s) that the Treating Healthcare Provider was consulted, retained, and/or compensated.

3. State the nature of the affiliation.

4. State the amount of money, grant, or honorarium paid to the Treating Healthcare Provider.

| **Treating Healthcare Provider** | **Date Consulted, Retained, or Compensated** | **Nature of Affiliation** | **Amount of Money, Grant, or Honorarium Paid** |
|---|---|---|---|
| | | | |
| | | | |

B. For each Treating Healthcare Provider identified in response to III.A., please identify and produce all consulting agreements, contracts, and/or retainer agreements between the Treating Healthcare Provider and GSK.

Response:

_____

_____

## IV. OTHER CONTACT WITH PLAINTIFF'S TREATING HEALTHCARE PROVIDER(S)

For each Treating Healthcare Provider, please state the following:

A. Other contact with Plaintiff's Treating Healthcare Provider(s): To the extent it is referenced in a call note or through records of payments to Treating Healthcare Providers and identifiable, if the Treating Healthcare Provider has spoken at or attended any Continuing Medical Education courses (CMEs), conferences, lunches, dinners, movie nights, or other presentations sponsored in full or in part by GSK in which Zofran®, Ondansetron, and/or Ondansetron Hydrochloride was

specifically discussed, please:

1. Identify the Treating Healthcare Provider.

2. Identify the date that the Treating Healthcare Provider attended and topic of said event.

3. State whether the Treating Healthcare Provider was a speaker or attendee.

| **Treating Healthcare Provider** | **Date of Event** | **Speaker or Attendee** |
|---|---|---|
| | | |
| | | |
| | | |

B. For any Treating Healthcare Provider identified in response to IV.A., please identify and produce all PowerPoints, documents, pamphlets, or correspondence used and/or provided at the event by GSK and/or any speaker(s) lecturing on behalf of GSK concerning the potential benefits, risks and/or warnings related to Zofran®, Ondansetron, and/or Ondansetron Hydrochloride use in pregnant women and/or morning sickness.

Response:

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## V. PLAINTIFF'S TREATING HEALTHCARE PROVIDERS' PRACTICES

For each Treating Healthcare Provider, please state whether you have in your possession prescriber-level information reflecting the Treating Healthcare Provider's prescriptions written for Zofran®, Ondansetron, and/or Ondansetron Hydrochloride, including but not limited to the product(s) prescribed, the number of prescriptions, the number of refills, and the timeframe when these products were prescribed or refilled.

Yes _____ No _____

If "Yes," please produce such documentation that may be permissibly provided under any applicable licensing agreements.

Response:

_____

_____

## VI. PLAINTIFF'S MEDICAL CONDITION

A. Other than in connection with any adverse event report, has GSK initiated contact with Plaintiff(s) or any of Plaintiffs' healthcare providers concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

_____

B. Other than in connection with any adverse event report, has GSK been contacted by Plaintiff(s), any of Plaintiffs' healthcare providers or anyone acting on Plaintiffs' behalf (other than Plaintiffs' counsel) concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or alleged injuries at issue in this lawsuit?

Yes _____ No _____

If yes, please identify the name and last known address of the individual(s) from GSK who had such contact and date of contact:

Response:

_____

_____

C. Please identify by document number and produce all non-privileged documents that reflect any communication between any person identified in Section VI.A. or VI.B. above and GSK concerning Plaintiffs.

Response:

_____

D. Please produce a copy of any Adverse Event Report or MedWatch form concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit as well as any underlying documentation, including, but not limited to, the adverse event source file, causality assessments, medical records, and non-privileged investigative reports that refers or relates to Plaintiff(s) or Minor Plaintiff.

Response:

_____

_____

E. Please identify by document number and produce any non-privileged surveillance, information, investigation, analysis, report, or any other internal information or documentation concerning Minor Plaintiff's Mother's use of Zofran®, Ondansetron, and/or Ondansetron Hydrochloride and the claims and/or the alleged injuries in this lawsuit

Response:

_____

_____

## CERTIFICATION OF COUNSEL

I, the undersigned counsel for GSK, certify under penalty of perjury that the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge, information, and belief and that I have engaged in best efforts to identify, locate, and supply all of the documents requested in this Defendant Fact Sheet.

Further, I acknowledge that I have an obligation to supplement the above responses, in accordance with the Federal Rules of Civil Procedure, if I learn that they are in some material respect incomplete or incorrect.

_____
Signature

_____
Printed Name

_____
Law Firm and Address

_____
Date