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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

**IN RE INCRETIN-BASED THERAPIES  
PRODUCTS LIABILITY LITIGATION**

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*This Document Relates to All Cases*

Case No. 3:13-md-02452-AJB-MDD  
MDL 2452

**PARTIES' JOINT SUBMISSION  
RE: SCIENCE DAY**

Judge: Hon. Anthony J. Battaglia  
Courtroom: 3B

1           Having met and conferred concerning the format for Science Day, the parties  
2 have reached agreement on the structure of Science Day(s) in several respects and  
3 have reached an impasse on two issues. The areas of agreement and dispute are set  
4 out below:

5           **Agreed Issues.** The parties agree on the following points:

- 6           • The purpose of Science Day is to apprise the Judges in both the MDL  
7 and the JCCP, in a non-adversarial manner, of the nature of diabetes as a  
8 disease, the treatment generally necessary for persons afflicted with  
9 diabetes, the role of Incretin-based therapies in treating diabetes and the  
10 mechanisms by which they work, pancreatic cancer and what, if any,  
11 effect the use of Incretin-based therapy may have in increasing the  
12 propensity to develop pancreatic cancer, along with the terminology  
13 likely to be employed in this litigation in addressing these issues. The  
14 parties will endeavor to address such issues as (1) what is Type 2  
15 diabetes; (2) pharmacological issues, i.e. what the drugs do; (3)  
16 pancreatic cancer and associated mortality and morbidity; and (4) data  
17 regarding pancreatic effects of incretin-based therapies.
- 18           • Lead Counsel for Plaintiffs and Counsel for Defendants respectively shall  
19 be responsible for designating those individuals, including Counsel with  
20 cases pending in the JCCP, who will make presentations on the various  
21 topics.
- 22           • A court reporter and videographer shall record the presentations and  
23 provide the respective Courts and the presenting party with copies of the  
24 party's respective transcription/video recording for future reference by  
25 the Judges or their Clerks. Any such recordings shall be treated as  
26 Confidential under the Protective Order. Each party shall maintain  
27 custody of its own copies and shall not be required to exchange them  
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1 with anyone other than the Court. These shall be the only recordings of  
2 any form made of the presentations. No counsel or any other person  
3 shall utilize any other form of recording during the proceedings.

- 4 • Science Day presenters will not be placed under oath. Nor, will  
5 presenters be subject to cross examination. If, for some reason, a  
6 presenter becomes a witness in the litigation, the presentation may not be  
7 used to cross examine or impeach the presenter since the purpose of  
8 presentations are intended solely to educate the Courts about the  
9 scientific issues in the litigation.
- 10 • The Presentations shall be deemed “off the record” for all purposes.
- 11 • The presentations shall not include any testimony from, or information  
12 about, specific Plaintiffs or cases.

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15 **Disputed Issues.** The parties have not reached agreement on the following  
16 issues. The parties’ respective positions on each of the disputed issues are set out  
17 below:

- 18 • **Should the parties submit “Science Background Papers” to the**  
19 **Court in advance?**

20 Plaintiffs’ Position: Plaintiffs do not believe advance submissions are  
21 needed or appropriate for Science Day presentations. Advance briefing, or as  
22 Defense described it, “Science Background Papers” opens up issues as to  
23 page length, format, appendices, rebuttals, etc., and as such will overly  
24 complicate what should be simple presentations to the Court. Plaintiffs  
25 suggest a procedure identical to that followed in the Byetta JCCP, i.e., each  
26 side presents their view of the science at the hearing, and at the conclusion  
27 each party submits whatever it has presented in written format to the  
28

1           respective Court’s. In the spirit of the non-adversarial format this is done  
2           without an exchange between the parties or rebuttals.

3                     Defendants’ Position: Defendants propose that the parties submit  
4           “white papers” to the Court on January 22, 2014, two weeks in advance of  
5           Science Day, with no rebuttals. The purpose of these submissions would be  
6           to (i) introduce basic terms and scientific information and (ii) outline the  
7           issues that will be addressed in greater detail during Science Day – and  
8           thereby provide a foundation for understanding the presentations the Judges  
9           will be hearing and allow a focus on the issues that matter most. The  
10          presentations are likely to be chock-full of new information and a primer  
11          could assist the Courts in grappling with topics that are not pervasive in  
12          common conversation. Papers are also likely to sharpen the parties’  
13          presentations and allow those presentations to be more focused and less  
14          redundant if the parties know what information others intend to address and  
15          what positions they intend to take.

16  
17          •     **Should Science Day be organized around an agreed set of topics?**

18                     Plaintiffs’ Position: A Science Day was conducted in the JCCP Byetta  
19          Pancreatitis Litigation. Plaintiffs propose we follow the exact same  
20          approach utilized in those proceedings, which allowed the parties to present  
21          complex issues to the Court in a non-adversarial manner and in a format that  
22          was not so unduly restrictive that it amounted to a point-counter point  
23          presentation. Much like a trial, each party should be allowed flexibility to  
24          present its science in a manner of its choosing without tight time restrictions  
25          by topic. Accordingly, similar to the JCCP precedent, Plaintiffs propose an  
26          agenda along the following lines that will allow questions and answers from  
27          the Court during the presentations without unduly limiting the time needed  
28          by each side make its presentation:

1                    February 5, 2014

2                    9:00am-12:30pm—Plaintiffs’ Opening Presentation

3                    2:00pm--5:30pm—Defendants’ Opening Presentation

4                    February 6, 2014

5                    9:00am-12:30pm—Plaintiffs’ Presentation

6                    2:00pm--5:30pm—Defendants’ Presentation

7                    Defendants’ Position: There are a number of topics agreed to by the  
8 parties that are appropriate to Science Day. It seems sensible to identify  
9 them and order the presentations around them, with each party having the  
10 opportunity to offer its perspective. Under such a plan, the parties might  
11 begin with background issues, such as (i) the nature of diabetes, (ii) the  
12 variety of diabetes treatments, and differences between them, and (iii)  
13 pancreatic cancer. An overview of publicly available information regarding  
14 the pancreatic effects of incretin-based therapies could be the topic of  
15 discussion on the second day. Having this structure would permit the Courts  
16 to hear from the two sides topic-by-topic in an organized fashion. In  
17 Defendants’ view, presentations without an agenda would likely result in  
18 confusion and presentations that pass in the night. Accordingly, Defendants  
19 propose an agenda along the following lines:

20                    February 5, 2014

- 21                    • 9:00 a.m. – Plaintiffs’ Introductory Statement
- 22                    • 9:30 a.m. – Defendants’ Introductory Statement(s)
- 23                    • 10:00 a.m. – Defendants’ presentation(s) regarding type 2 diabetes
- 24                    • 10:45 a.m. – Break
- 25                    • 11:15 a.m. – Plaintiffs’ presentation regarding type 2 diabetes
- 26                    • 12:00 p.m. – Lunch
- 27                    • 1:15 p.m. – Defendants’ presentation(s) regarding incretin-based  
28                    therapies

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- 2:15 p.m. – Plaintiffs’ presentation regarding incretin-based therapies
- 3:15 p.m. – Break
- 3:45 p.m. – Plaintiffs’ presentation(s) regarding pancreatic cancer
- 4:30 p.m. – Defendants’ presentation(s) regarding pancreatic cancer
- 5:15 p.m. – Break for the day

February 6, 2014

- 9:00 a.m. – Plaintiffs’ presentation regarding non-clinical information
- 10:30 a.m. – Defendants’ presentation(s) regarding non-clinical information
- 12:00 p.m. – Lunch
- 1:15 p.m. – Defendants’ presentation(s) regarding clinical/observational information
- 2:30 p.m. – Plaintiffs’ presentation regarding clinical/observational information
- 3:45 – Break
- 4:15 p.m. – Plaintiffs’ Summary Statement
- 4:45 p.m. – Defendants’ Summary Statement
- 5:15 p.m. – Remaining questions from the Court/Break for the day

Dated: November 18, 2013

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Dated: November 18, 2013

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**SIGNATURE ATTESTATION**

I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories concur in the filing's content.

/s/ Amy J. Laurendeau  
Amy J. Laurendeau

