

EXHIBIT 6

- 1 f. Zyprexa (MDL 1596)
- 2 g. Vioxx (MDL 1657)
- 3 h. Gadolinium (MDL 1909)
- 4 i. Chantix (MDL 2092)
- 5 j. Pradaxa (MDL 2385)
- 6 k. Lipitor (MDL 2502)

7 3. As a member of the leadership in those matters, I also served as the
8 discovery Chair, Co-chair or a member of the discovery committee. I am experienced in
9 leading the pharmacovigilance discovery efforts against pharmaceutical and medical
10 device manufacturers, especially with regard to how manufacturers collect, investigate,
11 track and trend adverse events reported regarding their products. A key part of this
12 pharmacovigilance discovery effort involves obtaining the source documents for each
13 adverse event relevant to the litigation so a detailed review can be performed of each
14 adverse event. Another key aspect of pharmacovigilance discovery is obtaining and
15 analyzing the manufacturer's adverse event database(s).

16 4. I have also served as the lead trial attorney in other multiple-plaintiff
17 personal injury matters against pharmaceutical manufacturers involving allegations
18 similar to those in the matters listed above. These other multiple-plaintiff matters were
19 consolidated before individual state courts, although not formally coordinated as state
20 JCCP or federal MDL proceedings. These litigations include:

- 21 a. Ketek (Superior Court of New Jersey)
- 22 b. Cypher Drug-eluting stents (Superior Court of Florida)
- 23 c. Inferior Vena Cava Filter litigation (multiple jurisdictions)

24 **ADVERSE EVENT SOURCE FILES**

25 5. There are two types of discovery at issue in this motion: adverse event
26 source files and adverse event databases. Adverse event source files are often called
27 source documents, source data, back-up files, and/or source documentation.

1 6. For *pre-market* adverse events occurring in connection with clinical trials,
2 the underlying source documents will often include communications with the clinical trial
3 investigators, and evaluations by the manufacturer, investigators or others as to the cause
4 of the adverse event (for instance, was the adverse event caused by the study drug, by an
5 accident, or by something else entirely).

6 7. For *post-market* adverse events, the source files consist of the underlying
7 documentation from intake to file closure that leads to the manufacturer's preparation of
8 a summary that is submitted to the FDA, typically on a document called a MedWatch
9 form. A good analogy would be that a MedWatch form for an adverse event is like a
10 hospital discharge summary for an injured plaintiff – it is pretty short and does not have
11 much detail. Continuing with that analogy, an adverse event source file contains
12 everything a manufacturer knows about and did regarding an adverse event, much like a
13 complete medical chart contains everything a hospital knows about and did regarding an
14 injured plaintiff. Defendants say that to really know and understand what happened, they
15 need a complete medical chart for an injured plaintiff: admission history and physical,
16 nurses' notes, prescription records, doctors' orders, consult reports, doctors' notes, lab
17 reports, diagnostic studies, operative reports, etc. – all the things that ultimately form the
18 basis of the discharge summary. It is the same here for Plaintiffs. To really know and
19 understand what happened regarding an adverse event, Plaintiffs need its complete source
20 file – all the things that ultimately form the basis of the MedWatch summary, not just the
21 MedWatch summary itself.

22 8. All source documents (whether pre- or post-market) may include the
23 patient's relevant medical records; internal comments made by the manufacturer about
24 the event; emails to and from the patient's physicians; notes of telephone conversations
25 with the patient's physicians or other healthcare providers; notes regarding any expert's
26 review of the event; adjudications made by the manufacturer as to whether the adverse
27 event was considered related or unrelated to the use of its drug, and why; whether the
28 event is listed or unlisted in the product label; whether it is a serious or non-serious event;

1 whether the event requires expedited reporting to regulatory authorities; and whether the
2 report, singularly, or in combination with other similar events warrant further action by
3 the company to warn, recall or take other appropriate action (e.g., monitoring) to protect
4 future “users” of the drug or medical device.

5 9. The ability to perform a detailed review of adverse event source
6 documentation is central to Plaintiffs’ case because it allows Plaintiffs’ experts to analyze
7 and, when appropriate, dispute Defendants’ claims about the supposedly benign nature of
8 their drugs and the adequacy of their label. The source files provide the best evidence of
9 what actually happened with each pancreatic cancer adverse event. Source files should
10 also show whether all of the pancreatic cancers associated with Defendants’ drugs were
11 properly reported to the FDA. In this litigation, there are a number of reasons to believe
12 that certain pancreatic cancers associated with these drugs were not properly reported,
13 and that the number of pancreatic cancers overall has been underreported. *See, e.g.,*
14 Plaintiff’s Opposition to Defendants’ Preemption Motion, and Plaintiffs’ portion of the
15 Memorandum of Points and Authorities prepared for this motion. The only way for
16 Plaintiffs to answer these questions is to carefully review the source documents for each
17 pancreatic cancer adverse event associated with each Defendant. In addition, pursuant to
18 FDA guidance, even one “well-documented” adverse event can create a safety signal,
19 particularly if the event is rare. *See Ex. 7* to Points and Authorities brief. Adverse event
20 source files can provide the detailed information for such safety signals.

21 ADVERSE EVENT DATABASES

22 10. A manufacturer’s adverse event databases typically serve as a repository for
23 most or all of the adverse event source files associated with its drugs. Storing the
24 information electronically in a database makes it readily accessible and easy to search,
25 sort and analyze. These databases are used to track the rates of adverse events reported
26 over time, to determine trends in the reporting of adverse events, and to perform other
27 analyses relevant to those events.

1 For instance, a manufacturer may report in a MedWatch form that the adverse event was
2 not causally related to the use of its drug, when the source documents (e.g., medical
3 records and physician comments) show that the patient’s doctors actually felt the event
4 was related to the drug, or that further investigation was required before ruling on that
5 one way or the other. Lab data problematic for the manufacturer may be ignored or
6 downplayed; statements by doctors or others may be taken out of context; etc. The only
7 way to determine if a MedWatch form fairly and accurately characterizes an adverse
8 event is to review the underlying source documentation for that event.

9 14. A good example of how adverse event source documents can help find the
10 truth behind an erroneous MedWatch summary can be seen in **Ex. 19** to the Points and
11 Authorities brief. **Ex. 19** is a letter produced in a source file in the Zyprexa litigation. It
12 was originally produced as “confidential.” To the best of my recollection and belief, it
13 was de-designated as no longer confidential, and it was also used at trial, admitted into
14 evidence as Trial Exhibit 7731 in *State of Alaska v. Eli Lilly*, Case #3AN-06-05630C1, in
15 March 2008. The MedWatch summary for the adverse event associated with **Ex. 19** had
16 reported only one incident of diabetes. However, on review of the source documents and
17 the discovery of **Ex. 19**, it became apparent that the reporting physician had actually
18 reported eight (8) patients with diabetes believed to result from Zyprexa use, not just one.
19 Without the Plaintiffs’ ability to verify the MedWatch summary by reference to its source
20 file, this error would never have been caught by the FDA or anyone else. As stated
21 above, in my experience these types of mischaracterizations and misstatements on
22 MedWatch summaries are not at all uncommon. Given how rare pancreatic cancer is,
23 even one or two adverse events reported incorrectly – of which there is already evidence
24 in this MDL – could alone provide a basis for a pancreatic cancer warning. *See, e.g.,*
25 Plaintiff’s Opposition to Defendants’ Preemption Motion (Dkt. No. 443), pp. 20-22, and
26 Part II(E)(2)(a) of the Points and Authorities brief for the instant motion. This
27 underscores how important it is that the adverse event source documents be produced.
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1 15. In at least twelve (12) of the litigations I have been involved in as referred to
2 above, the source files were produced to Plaintiffs in either hard copies or databases, and
3 sometimes both. In some of those litigations, the source documentation for thousands of
4 adverse events was produced to Plaintiffs. These adverse event source documents and
5 databases contained the information the manufacturer used, or should have used, to
6 prepare the summary “MedWatch” forms that it submitted to the FDA.

7 16. Recently in the Chantix litigation, adverse event source documentation
8 stored in hard copy form was converted to electronic documents and produced to
9 Plaintiffs. Also, information stored in the manufacturer’s adverse event safety database
10 was exported into a readable and searchable database for Plaintiffs’ use, with the
11 identifying information for the patients and reporters redacted. *See* Chantix Discovery
12 Plan, p. 4, **Ex. 16** to Points and Authorities brief.

13 17. In the Pradaxa litigation, the underlying source documents for almost eight
14 thousand (8000) adverse events were produced to Plaintiffs. Also, multiple databases
15 were produced, including the defendant’s adverse event database (ARISg). It was
16 produced to the Plaintiffs’ Steering Committee on:

17 “a virtual machine loaded with the full worldwide Pradaxa case data from
18 ARISg5 database.... The virtual machine produced by [the defendants] shall
19 provide the PSC with the same general capabilities that Defendants have
20 with regard to the ARISg5 database (e.g., the ability to search the database,
21 sort the data, save searches and results, view case history, print search
22 results, and extract data from the database). Notwithstanding the above, the
23 ARISg5 database is being produced with the understanding that the PSC will
24 not be receiving the proprietary ARISg5 application program and any
25 corresponding or associated user interface capabilities. [Defendants] shall be
26 permitted to withhold or redact the production of any patient or reporter
27 identifying information (name, street address (but not city or state), phone
28 number, email address, and social security number) in order to comply with
federal and European regulations....”

See Pradaxa Amended CMO No. 17, pp. 2-3, **Ex. 18** to Points and Authorities brief.

1 18. As in the Pradaxa, Chantix and other litigations referred to above, Plaintiffs
2 in this case seek the production of the adverse event databases and source documentation
3 that underlie the adverse event reports each Defendant submitted to the FDA. This type
4 of adverse event discovery has become common in complex pharmaceutical MDLs. It is
5 essential, and now commonplace, because it allows Plaintiffs to verify the accuracy of
6 Defendants' assertions about adverse events, and allows Plaintiffs to verify the
7 completeness and accuracy of the summaries (i.e., the MedWatch forms) provided by
8 each Defendant to the FDA.

9 19. I emphasize that Plaintiffs' request for production of the safety databases
10 Defendants use to store and track adverse event information internally is not unique or
11 unorthodox. On the contrary, the evidence contained in the requested files and databases,
12 as recognized by the courts and parties over the past three (3) decades, is not only highly
13 relevant, but critical in assessing virtually every aspect of Plaintiffs' case in chief,
14 including both general and specific causation. This evidence has been requested,
15 provided, and ultimately used by Plaintiffs' experts in all of the cases in which I have
16 participated as Plaintiffs' counsel as described in paragraph No. 2 above.

17 20. I and others working with me have reviewed the FDA adverse event
18 database for pancreatic cancer adverse events associated with Defendants' drugs through
19 the first quarter of 2013. The FDA database shows approximately 203 such events for
20 Merck; 335 for Amylin; and 206 for Novo (as of October 2013). Defendants' effort to
21 avoid producing all pancreatic cancer adverse event source documents is not only
22 unusual, but curious considering the low volume of those compared to other cases, as
23 detailed above and, in my view and my experience, it is not appropriate in this type of
24 litigation. The source files are necessary in order to provide a complete picture to
25 Plaintiffs' experts, who will provide opinions in support of Plaintiffs' claims, and who
26 must also rebut the claims made by Defendants. It is unfair to allow Defendants to fight
27 that "information battle" fully armed, while giving Plaintiffs only a fraction of the
28 available data.

1 21. Defendants have also suggested that the production of source files could be
2 limited to the files of the Plaintiffs only. This would be highly prejudicial to Plaintiffs. It
3 would deprive them of the full range of adverse event information already in the hands of
4 Defendants. It would also deprive them of the ability to perform and verify the adverse
5 event tracking, trending and other analyses done by Defendants, including causality
6 assessments, which are done using adverse event data “in the aggregate.” *See, e.g., Ex.*
7 **12** to Points and Authorities brief (Hostelley Dep. Tr., pp. 55:5-58:8; 61:4-17).
8 Moreover, the adverse event source files for a litigant – a Plaintiff – are typically *not*
9 representative of source files for non-litigants. The source files for adverse events
10 reported to a manufacturer through litigation tend to be much larger and much less
11 informative than non-litigation source files. Adverse events reported through litigation
12 typically contain just the pleadings, discovery, etc., of a normal litigation file, rather than
13 the type of detailed medical information, emails, follow-up, analyses, causality
14 assessments, internal discussions, etc., developed for adverse events when reported by the
15 patient or a patient’s medical provider. This reflects the fact that a Defendant’s
16 communication with a litigant’s medical providers is typically prohibited once a lawsuit
17 is filed. In short, while there is more paper in a typical litigant’s source file, it usually
18 provides far less useful information than a non-litigant’s file.

19 **PROPOSAL THAT PLAINTIFFS BE REQUIRED TO PAY FOR SOURCE DOCUMENTS**

20 22. Adverse event source documents and databases are a normal part of
21 discovery in pharmaceutical litigation and a normal litigation expense for drug
22 manufacturers, not an excuse for cost-shifting. Moreover, the redaction work is
23 ministerial; it need not be done by attorneys; and it need not be done for the Plaintiffs’
24 pancreatic cancer files at all, which are a significant subset of the pancreatic cancer
25 adverse event files. The actual costs of redaction should be only a fraction of what
26 Merck claims they will be.
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1 I declare under penalty of perjury that the foregoing is true and correct.

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3 Executed on August 12, 2014.

s/ Ramon Lopez
4 RAMON ROSSI LOPEZ
5 Lopez McHugh LLP
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