

1 June 23, 2011, the Court approved the parties' stipulation to
2 vacate all case management deadlines and stay discovery until
3 after the parties' mediation or the ruling on Defendants' motions
4 for summary judgment, whichever occurs later, and at that time to
5 determine a proposed schedule for the remainder of the case.

6 Subsequently, Defendants Abbott Laboratories, GSK, TEVA
7 Pharmaceuticals USA, which includes Gate Pharmaceuticals, and PAR
8 Pharmaceutical, Inc., moved for summary judgment on the grounds
9 that Plaintiffs lacked evidence to establish proximate causation.
10 Docket Nos. 177, 179, 183 and 185. Abbott manufactures, markets,
11 distributes and sells Humira. TEVA distributes 6-MP products that
12 have been resold in California and has marketed and advertised the
13 product under the brand name Purinethol. GSK manufactured,
14 labeled, packaged and marketed Purinethol in the United States
15 prior to July 2003. PAR distributes 6-MP in California. These
16 Defendants argued that Plaintiffs lacked evidence to show that a
17 different warning would have changed the treating physician's
18 decision to prescribe Humira and 6-MP to Maxx. Defendants Johnson
19 & Johnson and its wholly owned subsidiary, Centocor, Inc., which
20 manufactured, marketed, sold and distributed Remicade, did not
21 file motions for summary judgment at that time. On December 15,
22 2011, the Court granted summary judgment in favor of Abbott, GSK,
23 TEVA and PAR.

24 After the Court's ruling, Johnson & Johnson and Centocor
25 moved for summary judgment, arguing that Plaintiffs lacked
26 evidence to establish that a failure to warn of the risk
27 associated with Remicade caused harm to Maxx. Docket No. 205.
28 Johnson and Johnson also argued that it was not involved with the

1 research, production, marketing or distribution of the drug.
2 After briefing on the second motion for summary judgment was
3 completed, Plaintiffs moved for leave to file a motion for
4 reconsideration of the Court's December 15, 2011 order. Docket
5 No. 220. Plaintiffs argued that new evidence presented in
6 connection with the second motion for summary judgment warranted
7 reconsideration. Abbott, GSK and TEVA opposed the request for
8 reconsideration. On April 12, 2012, the Court granted Plaintiffs'
9 request for leave to file a motion for reconsideration and allowed
10 Defendants to file additional briefing.

11 Having considered all of the parties' submissions and oral
12 argument, the Court denies Centocor and Johnson and Johnson's
13 motion for summary judgment. In addition, the Court grants
14 Plaintiffs' motion for reconsideration of its December 15, 2011
15 order and, upon reconsideration, denies Abbott's, TEVA's and PAR's
16 motions for summary judgment. The Court grants GSK's March 2,
17 2011 motion for summary judgment on the grounds that it
18 discontinued its sales of Purinethol in 2003, before its risks
19 were known.

20 BACKGROUND

21 In the fall of 1998, Maxx was diagnosed with inflammatory
22 bowel disease (IBD), and began receiving treatment from Dr. Edward
23 Rich, a pediatric gastroenterologist at Kaiser Permanente in San
24 Francisco. Rich Dep. at 50:5-10, 59:22-60:1, 74:23-25.³

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27 ³ The complete transcript of the deposition is located at
28 Docket No. 199.

1 Dr. Rich testified that it was not his "regular practice to
2 look at drug labeling." Id. at 192:6-7. He received information
3 on medications from multiple sources, including conferences and
4 large meetings with pediatric gastroenterologists and adult IBD
5 specialists, as well as smaller regional meetings and dinner
6 meetings with these colleagues. Id. at 251:5-252:2. Dr. Rich
7 also gained knowledge about therapies from discussions with other
8 professionals in the field, articles and occasional meetings with
9 drug representatives. Id. at 192:7-14. He explained, "Generally
10 I'm looking at drug labeling or the PDR in medicines that I'm less
11 familiar with."

12 With respect to the impact of drug labeling on his decisions
13 regarding treatment, Dr. Rich testified, "Drug labeling is
14 sometimes something I rely on when making decisions on drug use
15 for patients." Id. at 190:21-23. He stated, "When I read the
16 labeling, it's one of the things that is part of my decision-
17 making process." Id. at 191:20-22. Dr. Rich could not remember
18 whether he ever relied on labeling information for 6-MP before
19 prescribing it to patients. Id. at 282:2-283:2.

20 In June 1999, Maxx began taking 6-MP, an immunosuppressive
21 medication. Id. at 105:14-15. Dr. Rich prescribed varying
22 dosages of 6-MP, while attempting to wean Maxx from Prednisone, a
23 steroid. However, as of May 2002, Maxx was still taking
24 Prednisone and 6-MP. Id. at 117:4-11.

25 At the time Dr. Rich prescribed 6-MP he was aware of a paper
26 reporting the occurrence of lymphoma in adults taking the drug.
27 Id. at 89:12-90:17. According to Dr. Rich, the frequency of
28 lymphoma occurrences reported in the study was one in one hundred

1 adult patients taking 6-MP. Id. at 89:23-90:4. Dr. Rich found
2 this "significant," prompting him to warn patients of a "small but
3 non-zero increased risk of serious infections or malignancies"
4 when discussing 6-MP treatment. Id. at 89:2-90:17. Dr. Rich
5 testified that he may or may not have included the word "lymphoma"
6 when providing the warning. Id. at 89:7-12.

7 At an appointment with Maxx on May 8, 2002, Dr. Rich
8 discussed in detail prescribing Remicade. Id. at 117:4-118:1.
9 Again, the goal in changing Maxx's medication at this time was to
10 take him off steroids. Id. at 151:17-152:9. On July 10, 2002,
11 Maxx received his first infusion of Remicade. Id. at 147:24-
12 148:16. Maxx received infusions of Remicade approximately every
13 three months thereafter, in combination with 6-MP. Id. at 155:4-
14 12, 157:9, 170:12-21.

15 Dr. Rich considered Remicade, as well as Humira, part of a
16 class of anti-tumor necrosis factor (TNF) drugs, also known as TNF
17 inhibitors. Id. at 175:10-14, 176:9-17, 264:24-25, 265:2-3. He
18 testified that he "virtually always" informed his patients of a
19 "nonzero increased risk" of serious infections and malignancies
20 related to "immunosuppressives and anti-tumor necrosis factor
21 drugs." Id. at 123:6-10. According to Dr. Rich, at a point in
22 time he could not recall, he became aware of a study involving
23 approximately 700 patients on Remicade therapy, a majority of whom
24 had rheumatoid arthritis and a minority of whom had Crohn's
25 disease. Id. at 125:13-19. The study reported incidents of
26 serious infections and malignancies, including lymphomas, within
27 that patient population. Id. at 125:20-126:1. This is consistent
28 with an entry regarding Remicade in the 2002 Physicians' Desk

1 Reference, which included mention of a clinical study involving
2 771 patients, seven of whom developed new or recurrent
3 malignancies, including lymphoma. Id. at 133:2-12. However, the
4 PDR also stated that "the observed rates and incidents [of these
5 malignancies] were similar to those expected for the population."
6 Id. at 133:10-12. According to Dr. Rich, in 2002 there were no
7 reports on the risk of therapies combining Remicade and 6-MP. Id.
8 at 132:10-12.

9 In February 2005, the first case report was published of an
10 IBD patient with hepatosplenic T-cell lymphoma who had received
11 immunosuppressive therapy in combination with Remicade.⁴
12 Declaration of Kevin Haverty in support of Plaintiffs' Opposition,
13 Ex. 4, Rosh Report, at 5. Hepatosplenic T-cell lymphoma is a
14 rare, incurable, aggressive cancer that is nearly always fatal.
15 Id. at 2-3. Of eight cases of young patients diagnosed with
16 hepatosplenic T-cell lymphoma reported to the federal Food and
17 Drug Administration (FDA), six died. Defendant Abbott Labs, TEVA
18 and Par's Further Opposition to Plaintiffs' Mot. for
19 Reconsideration, Ex. 2, FDA Short Communication, at 265. Each of
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22 ⁴ The first case report was "Hepatosplenic T-cell lymphoma in
23 an adolescent patient after immunomodular and biologic therapy for
24 Crohn's disease," authored by Thayu M., Markowitz J.E., Mamula P.,
25 et al. (Thayu Report), and published in the Journal of Pediatric
26 Gastroenterology and Nutrition. The Thayu Report refers to
27 infliximab, another name for Remicade, see e.g., Jones Affidavit,
28 Ex. G, May 2006 Remicade Package Insert, at 1, and describes
immunomodulatory and biologic therapy as treatment combining 6-MP
and Remicade. A May 2007 report entitled, "Hepatosplenic T-cell
lymphoma in adolescents and young adults with Crohn's disease: A
cautionary tale?," authored by Rosh J.R., Gross T., Mamula P.,
Griffiths A. and Hymans J. (Rosh Report), referred to the Thayu
Report as the first such case report. Haverty Dec., Ex. 4 at 5.

1 the patients succumbed to the cancer within a year or less from
2 the time of diagnosis. Id. at 266.

3 In November 2005, Centocor submitted to the FDA a
4 supplemental Biologic License Application (sBLA) seeking approval
5 of a new use of Remicade for treatment of pediatric Crohn's
6 disease.

7 Also in November 2005, Dr. Rich began to consider
8 discontinuing Maxx's Remicade treatment and discussed Humira with
9 him. Id. at 170:24-173:5. Dr. Rich testified that in "late 2005"
10 he became aware of a "complication" associated with Remicade,
11 namely the occurrence of hepatosplenic T-cell lymphoma in
12 adolescent and young adult patients taking Remicade with 6-MP.
13 Id. at 204:21-205:22, 215:3-4.

14 In his deposition, Dr. Rich was not asked directly about the
15 source of his knowledge about the complication, but he testified,

16 I knew this information before the black box warning
17 or messaging from the patient (verbatim). I was aware
18 of literature as it evolved. This is a very important
19 part of our treatment. And was aware from many
20 sources when cases first got--were first reported,
21 came to my attention. I believe that was sometime in
22 2005. I can't tell you when . . .

23 I can't remember exactly the time course of what I
24 learned and where. At some point I became aware of
25 cases of hepatocellular [sic] T-cell lymphoma in young
26 males on combination therapy of Remicade and
27 immunosuppressive therapy. And at some point, there
28 was a report. I can't--I don't remember if it was
first at a meeting--I didn't attend the meeting, if
that was true--or if it was an abstract or if it was
just a case report of a number of patients.

The number in my head is something like six patients
with this rare or uncommon lymphoma. And then at some
point there was an article on this, I believe. At
first it might have been a report and then an article,

1 but I can't exactly be sure. And when the article
2 came out it was six to eight patients, and this was
before the black box warning came out.

3 Id. at 205:15-23; 206:12-207:5.

4 When asked whether any doctor had discussed a case of
5 hepatosplenic T-cell lymphoma with him, Dr. Rich testified that he
6 may have learned of such a case from a colleague in the East Bay
7 and a doctor from Atlanta. Id. at 29:24-32:5. Dr. Rich did not
8 recall the specific date or month when the conversations occurred.
9 He testified repeatedly that he did not remember when his informal
10 discussion with the Atlanta-based physician occurred. At one
11 point, he stated that the discussion may have occurred in the late
12 1990s, but then retracted this and testified that he learned of
13 the case "when patients with side effects were being reported, but
14 not many, so that would be approximately the mid-2000s." Id. at
15 32:21-35:6. Dr. Rich also testified that when Maxx's case was
16 discussed with his regional pediatric gastroenterology group,
17 which met quarterly, a pediatric gastroenterologist from the East
18 Bay may have mentioned such a case. Id. at 15:5-25.

19 Maxx received an infusion of Remicade in November 2005 and
20 then his final dose of Remicade in March 2006. Id. at 182:15-14;
21 197:16-199:7. Between February 2005 and February 2007, nine cases
22 of hepatosplenic T-cell lymphoma in IBD patients receiving
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1 combination therapy were confirmed, in addition to Thayu's case.⁵
2 Rosh Report at 5.

3 In April 2006, as part of Centocor's sBLA and the FDA's
4 review of the application, a safety signal was identified for
5 hepatosplenic T-cell lymphoma. Affidavit of Stella Jones at ¶ 11.
6 As defined by the FDA in a guidance document, a safety signal
7 "refers to a concern about an excess of adverse events compared to
8 what would be expected to be associated with a product's use."
9 Id. at ¶ 12. Safety signals may arise from post-marketing data
10 and other sources, and even a single well-documented case report
11 can be viewed as a signal. Id. Centocor's submission did not
12 reveal the nature of the safety signal. In Abbott, TEVA and PAR's
13 further opposition to Plaintiffs' motion for reconsideration,⁶
14 they state that, in addition to the first case report published in
15 February 2005, there were five cases reported to the FDA's Adverse
16 Event Reporting System (AERS) through May 2006, when Centocor
17 added the black-box warning to the Remicade label and distributed
18 a "Dear Healthcare Provider" letter to physicians.

21 ⁵ The Rosh Report examined ten incidents of hepatosplenic T-
22 cell lymphoma in young patients receiving Remicade in combination
23 with 6-MP or azathioprine (AZA), the parent compound of 6-MP.
24 Rosh Report at 2, 6. The Rosh Report cited Centocor data as well
25 as an FDA "Short Communication" authored by researchers from the
26 Center for Drug Evaluation and Research, a part of the federal
27 agency. The Short Communication was published in February 2007 in
28 the Journal of Pediatric Gastroenterology and Nutrition.
Defendants Abbott, TEVA and Par's Further Opposition to
Plaintiffs' Mot. for Reconsideration, Ex. 2.

⁶ Centocor and Johnson & Johnson, as well as GSK, joined the
arguments made in this opposition brief. Docket Nos. 229 and 230.

1 In May 2006, the FDA approved the new use of Remicade for
2 reducing signs and symptoms and inducing and maintaining clinical
3 remission in pediatric patients with moderately to severely active
4 Crohn's disease who have had an inadequate response to
5 conventional therapy. Jones Affidavit at ¶ 14. However, the FDA
6 also required the addition of the following black box warning:

7 RARE POSTMARKETING CASES OF HEPATOSPLENIC T-CELL
8 LYMPHOMA HAVE BEEN REPORTED IN ADOLESCENT AND YOUNG
9 ADULT PATIENTS WITH CROHN'S DISEASE TREATED WITH
10 REMICADE. THIS TYPE OF T-CELL LYMPHOMA HAS A VERY
11 AGGRESSIVE DISEASE COURSE AND IS USUALLY FATAL. ALL OF
12 THESE HEPATOSPLENIC T-CELL LYMPHOMAS WITH REMICADE HAVE
13 OCCURRED IN PATIENTS ON CONCOMITANT TREATMENT WITH
14 AZATHIOPRINE OR 6-MERCAPTOPYRIMIDINE.

15 Haverty Dec., Ex. 3.

16 Dr. Rich testified that he would have received this black box
17 warning in the form of a letter or other notification at about the
18 time it was issued. Rich Dep. at 214:23-215:3.

19 Also in May 2006, Maxx underwent a colonoscopy that revealed
20 no signs of IBD. Id. at 198:1-199:14. According to Dr. Rich, a
21 decision to discontinue Remicade or use an alternative medication
22 would have been made at the time of the colonoscopy, based on the
23 results of the examination. Id. at 172:10-12. Maxx received no
24 further infusions of Remicade.

25 As of October 5, 2006, the AERS had received notice of eight
26 young patients with Crohn's Disease and ulcerative colitis who
27 received Remicade with concomitant immunosuppressant therapy,
28 including 6-MP in some cases, and developed hepatosplenic T-cell
lymphoma. Abbott, TEVA and Par's Further Opposition to
Plaintiffs' Mot. for Reconsideration, Ex. 2, FDA Short
Communication.

1 By November 2006, Maxx experienced a relapse. On November
2 22, 2006, he received his first prescription for Humira, taking
3 the drug in combination with 6-MP. Id. at 217:14-16. Dr. Rich
4 testified that he first treated patients with Humira in early 2005
5 or 2006 when two sixteen-year-old female patients with IBD
6 received the drug. Id. at 193:3-7; 173:19-25. Dr. Aileen Dillon,
7 a rheumatologist, wrote Maxx's first prescription for Humira
8 because, when Humira was first placed on the Kaiser formulary, it
9 was placed under limited release, only through rheumatologists.
10 Id. at 217:14-218:6. Dr. Rich testified that when he first began
11 prescribing Humira to his patients, he warned them of a "nonzero
12 but increased risk of serious infections and malignancies." Id.
13 at 193:23-194:11. His awareness of this risk was based on
14 literature he had reviewed and discussions he had had with other
15 physicians. Id. at 194:12-18.

16 When asked why he did not treat Maxx with Remicade in
17 November 2006, Dr. Rich responded,

18 So in November '06, we had been aware for some time of
19 complication of hepatosplenic T-cell lymphoma, so that
20 would have been part of my discussion with the family.
Ease of therapy is always a discussion with Humira
versus Remicade.

21 Id. at 218:13-23. Dr. Rich explained that Humira may be
22 administered by the patient or a family member at home through
23 subcutaneous injections, while Remicade requires a patient to
24 visit a facility for two to three hour infusions. Id. at 174:15-
25 19, 267:5-23.

26 When asked whether he opted for Humira because of the black
27 box warning concerning Remicade, Dr. Rich testified, "I think that
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1 the concern of hepatosplenic T-cell lymphoma would have been part
2 of my discussion with the family and it would have been part of my
3 thinking about the use of this disease (verbatim).” Id. at
4 219:16-22. Dr. Rich did not recall any similar warning regarding
5 Humira’s use in combination with 6-MP and hepatosplenic T-cell
6 lymphoma. Id. at 219:23-220:2. Dr. Rich did not state that he
7 would not have prescribed Humira in November 2006, had there been
8 a black box warning or similar alert regarding the use of Humira,
9 alone or in combination with 6-MP, and the occurrence of
10 hepatosplenic T-cell lymphoma. Maxx’s mother, Lisa Wendell,
11 testified that Dr. Rich never informed her of the black box
12 warning concerning Remicade, but told her that Humira had a better
13 safety profile, in addition to being easier to administer.
14 Haverty Dec., Lisa Wendell Dep. at 77:4-13.

15
16 In deposition, Dr. Rich was asked whether his drug
17 recommendation was informed by the fact that Remicade had a black
18 box warning about a rare, aggressive cancer, while Humira did not.

19 Dr. Rich responded,

20
21 I don’t think the black box would have been a primary
22 driving point in the use of medicine, just as FDA
23 indication or not is not a driving point, as FDA
24 doesn’t indicate very much of anything in pediatrics.

25 Id. at 220:1-15.

26
27 Later, Dr. Rich was asked again whether information that he
28 had about the cases of hepatosplenic T-cell lymphoma associated
with Remicade and 6-MP combination use informed in any way his

1 recommendation that Maxx start Humira in November 2006. He
2 answered,

3 The occurrence of hepatosplenic T-cell lymphomas and
4 the information and knowledge about that would have
5 been part of many things that would have gone into my
6 own thinking on how to use this--these medications and
7 my discussion with the patients on how to use these
8 medications.

9 Id. at 225:7-113.

10 In addressing whether all anti-TNF drugs carry the same
11 risks, Dr. Rich testified that Humira was "entirely humanized,"
12 whereas Remicade was "75 percent humanized and 25 percent mouse."

13 Id. at 194:24-25. Dr. Rich engaged in the following exchange with
14 counsel,

15 A: So I presented [anti-TNF] medications always as
16 having an increased but nonzero increased risk. And
17 if I was asked by a patient, "Why do you use one
18 versus the other," or why we were considering Humira,
19 it may have come up in discussions that Humira was
20 fully humanized and may have--my statement would have
21 --would have been, "It may have a better safety
22 profile."

23 Q: What was the basis of your thinking that it may
24 have a better safety profile?

25 A: That it was fully humanized.

26 Q: What--

27 A: That there are allergy side effects to these
28 medicines.

Q: Okay. Other than allergies, did the fact that
Humira was fully humanized, monoclonal antibody, as
opposed to Remicade, affect, in your mind, the risk of
malignancies?

A: I can't recall whether I thought that or not. The
fact that there--I'm not an immunologist, and I'm not
sure they can answer that question. But the fact that
there is no mouse suggests that it might have been a
consideration in my thinking, that it's a possibility.

Id. at 195:13-196:12.

1 When asked if he had "an opinion about whether or not Humira
2 had a better safety profile than Remicade for use in combination
3 therapy with 6-MP" with respect to the risk of hepatosplenic T-
4 cell lymphoma, Dr. Rich responded,

5 I don't believe I had an--an opinion. There was a--
6 had been a thought, as I said, that Remicade may--
7 Humira, excuse me, may have a better safety profile.
8 And I don't remember what I thought or didn't think or
9 knew about cases in November of '06. But I don't
10 believe there had been cases reported at that time of
11 patients with Humira developing hepatosplenic T-cell
12 lymphoma. So it would have been a possibility in my
13 mind that it had a better safety profile, and I would
14 have said that to a patient.

15 Id. at 226:21-227:7.

16 Based on Dr. Rich's recommendation, Maxx took Humira for at
17 least eight months. In mid-July 2007, Maxx was diagnosed with
18 hepatosplenic T-cell lymphoma. In December 2007, he passed away.

19 As noted earlier, in February 2007, the FDA published a Short
20 Communication in the Journal of Pediatric Gastroenterology and
21 Nutrition, authored by researchers from the agency's Center for
22 Drug Evaluation and Research. Defendants Abbott, TEVA and Par's
23 Further Opposition to Plaintiffs' Mot. for Reconsideration, Ex. 2.
24 The Short Communication reported that, as of October 5, 2006, the
25 AERS had received notice of eight young patients with Crohn's
26 Disease and ulcerative colitis who received Remicade with
27 concomitant immunosuppressant therapy, including 6-MP in some
28 cases, and developed hepatosplenic T-cell lymphoma.

 In May 2007, as previously mentioned, the Rosh Report was
published. It examined ten incidents of hepatosplenic T-cell

1 Material facts which would preclude entry of summary judgment
2 are those which, under applicable substantive law, may affect the
3 outcome of the case. The substantive law will identify which
4 facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S.
5 242, 248 (1986).

6 DISCUSSION

7 I. Centocor and Johnson & Johnson's Motion for Summary Judgment

8 Under the learned intermediary doctrine, a manufacturer of a
9 prescription drug is obliged to warn doctors, not patients, of
10 potential side-effects associated with its pharmaceutical
11 products. Carlin v. Superior Court, 13 Cal. 4th 1104, 1116
12 (1996). A manufacturer of prescription drugs discharges its duty
13 to warn if it provides an adequate warning to the physician about
14 any known or reasonably knowable dangerous side effects of a
15 medicine, regardless of whether the warning reaches the patient.
16 Carlin, 13 Cal. 4th at 1116-17. A plaintiff asserting causes of
17 action for failure to warn must prove not only that no warning was
18 provided or that the warning was inadequate, but also that the
19 inadequacy or absence of a warning caused the plaintiff's injury.
20 Plummer v. Lederle Laboratories, 819 F.2d 349, 358 (2d Cir. 1987)
21 (applying California law). Under Motus v. Pfizer, Inc., 358 F.3d
22 659, 661 (9th Cir. 2004), "a product defect claim based on
23 insufficient warnings cannot survive summary judgment if stronger
24 warnings would not have altered the conduct of the prescribing
25 physician."

26 Centocor asserts that it is entitled to summary judgment
27 because its warnings concerning Remicade were adequate in that the
28 labels had long advised of the risk of lymphomas associated with

1 the drug. However, Plaintiffs' claim is based on Centocor's
2 alleged failure to warn of the risk of hepatosplenic T-cell
3 lymphoma, a rare type of lymphoma that is nearly always fatal.
4 Furthermore, pursuant to the parties' stipulation, the summary
5 judgment motions at this time are to address the issue of
6 proximate causation. If the case is not disposed of on the issue
7 of proximate causation, discovery and litigation on other issues,
8 such as the adequacy of the labeling will proceed. Plaintiffs
9 correctly note that as a result of the discovery stay they have
10 been unable to depose Dr. Stella Jones, who submitted an affidavit
11 concerning Remicade label changes. Thus, they have been unable to
12 uncover what was known to Defendants about lymphomas at the time
13 labels were issued. The purported adequacy of the labeling, at
14 this point in time, is not a basis for granting summary judgment
15 in favor of Centocor.

16 Centocor also argues that Plaintiffs cannot establish
17 proximate causation because Dr. Rich was already aware, as of
18 "late 2005," of the occurrence of hepatosplenic T-cell lymphoma in
19 adolescent and young adult patients taking Remicade with 6-MP, but
20 he continued to prescribe the medications together. Plaintiffs
21 point to medical literature to dispute Dr. Rich's testimony on
22 this point. Dr. Rich's explanation of the course of events as he
23 learned of the risk of hepatosplenic T-cell lymphoma could support
24 a finding that he did not learn of it until after late 2005,
25 perhaps not until the black box warning in May 2006. Dr. Rich
26 stated that he could not remember the exact time and circumstances
27 when he learned of hepatosplenic T-cell lymphoma occurring in
28 young males receiving combination therapy. He testified that in

1 late 2005 he became aware of such cases, plural. Dr. Rich stated
2 that he did not recall if he first learned of the cases at a
3 meeting, but if the cases were reported at a meeting, he was not
4 in attendance. He recalled learning of approximately six
5 incidents from a case report or abstract, followed by further
6 reporting in an article. However, the Rosh Report indicates that,
7 as of February 2005, there was only one case report, the Thayu
8 Report, in the medical literature concerning such an incident.

9 It is not disputed that five additional cases were reported
10 to the FDA through AERS by May 2006. Yet, there is insufficient
11 evidence for a jury to infer reasonably that Dr. Rich learned of
12 the five cases before Maxx's last dose of Remicade in March 2006.
13 Dr. Rich testified that he learned about drug therapies from a
14 variety of sources. However, he did not state that he received
15 information about the AERS-reported cases from any large meetings,
16 conferences and smaller gatherings with colleagues. He testified
17 that he may have learned of two cases from discussions with
18 physicians based in the East Bay and Atlanta. However, Dr. Rich
19 evidently learned of the case from the East Bay physician after
20 Maxx was diagnosed with hepatosplenic T-cell lymphoma and
21 discussed such a case with the physician from Atlanta in the "mid-
22 2000s."

23 It was not until February 2007 and May 2007, respectively,
24 that the FDA Short Communication and the Rosh Report were
25 published. The Short Communication relayed that the AERS had
26 received notice of eight young patients receiving combination
27 therapy who developed hepatosplenic T-cell lymphoma. The Rosh
28 Report addressed ten such cases. Defendants have not pointed to a

1 publication earlier than February 2007 discussing the occurrence
2 of hepatosplenic T-cell lymphoma in multiple young patients
3 receiving combination therapy. Dr. Rich's description of his
4 knowledge is consistent with the February 2007 publication of
5 FDA's Short Communication, followed by the Rosh Report, published
6 in May 2007.

7 In sum, Plaintiffs have pointed to evidence that shows a
8 paucity of published information in 2005 and early 2006 concerning
9 the risk of hepatosplenic T-cell lymphoma for patients receiving
10 Remicade and 6-MP concurrently; Dr. Rich's poor memory as to when
11 he learned of the risk; and the chronology of relevant
12 publications in 2007, which reconciles with his description of how
13 he learned of such cases. Thus, the evidence is sufficient to
14 raise a material dispute of fact as to whether Dr. Rich was aware
15 of the risk before Maxx's last dose of Remicade and 6-MP in March
16 2006 and the May 2006 issuance of the black box warning.

17 Centocor seeks summary judgment on the grounds that any
18 failure to warn earlier did not cause harm to Maxx because Dr.
19 Rich was already aware of the risk. However, because of the
20 evidence from which it can be inferred that Dr. Rich learned of
21 the risk no earlier than May 2006, there is a material dispute of
22 fact as to whether Dr. Rich knew of the risk in late 2005.

23 Moreover, there is evidence indicating that, had Dr. Rich
24 known earlier of the risk of hepatosplenic T-cell lymphoma, he
25 would have decided against prescribing Remicade in combination
26 with 6-MP. Dr. Rich's testimony could be understood to imply that
27 his awareness of the risk of hepatosplenic T-cell lymphoma in
28 connection with Remicade and 6-MP influenced his decision to

1 prescribe Humira, rather than Remicade, when Maxx experienced a
2 relapse in November 2006. Further, Dr. Rich now prescribes
3 monotherapy only, after Maxx developed hepatosplenic T-cell
4 lymphoma while receiving combination therapy and after Dr. Rich
5 learned of the reports of the disease in young patients receiving
6 combination therapy. This raises a question of fact as to whether
7 an earlier warning of the risk would have influenced Dr. Rich to
8 change his prescribed treatment for Maxx.

9 This case is distinguishable from Plummer. In Plummer, the
10 Second Circuit, applying California law, found that judgment
11 should have been entered for the defendant, because the physician
12 knew of the risk for which the plaintiff sought a warning. The
13 court concluded that "no harm could have been caused by failure to
14 warn of a risk already known." 819 F.2d at 359. In contrast to
15 Plummer, there is a dispute of fact as to whether Dr. Rich already
16 knew of the risk of hepatosplenic T-cell lymphoma associated with
17 Remicade and 6-MP at the time the black box warning was issued.
18 This case is also distinguishable from Motus, where the treating
19 physician testified unequivocally that he neglected to read the
20 published warnings and did not rely on information from the drug
21 representatives before prescribing the medication that allegedly
22 induced the decedent to commit suicide. 385 F.3d at 661.

23 Summary judgment in favor of Centocor for lack of evidence of
24 proximate causation is unwarranted.

25 Johnson and Johnson, Centocor's parent company, moves for
26 summary judgment on the grounds that it has not been involved in
27 the research, development, marketing or manufacture of Remicade,
28 and that it has not controlled or dominated the activities of

1 Centocor to an extent that could give rise to parental liability
2 for failure to warn. In support of these contentions, Johnson and
3 Johnson has submitted a declaration by its Assistant Secretary,
4 Lacey Elberg, executed on August 30, 2011. Plaintiffs respond
5 that they have been unable to conduct discovery to explore the
6 facts attested to by Ms. Elberg. Although in general a parent
7 corporation is not liable for the acts of its subsidiaries, an
8 exception may apply where the corporate veil may be pierced
9 because "the corporate form would otherwise be misused to
10 accomplish certain wrongful purposes." United States v.

11 Bestfoods, 524 U.S. 51, 61-62 (1998). Discovery in this matter
12 has been stayed since June 23, 2011, pursuant to the parties'
13 stipulation. The parties agreed to stay discovery until after
14 their mediation or the resolution of their motions for summary
15 judgment, whichever occurred later. The parties stipulated that
16 further discovery would be scheduled in the event that the case
17 continued. Thus, Johnson and Johnson's motion for summary
18 judgment is premature and the Court denies it without prejudice.

19 II. Motion for Reconsideration

20 As noted earlier, Plaintiffs move for reconsideration of the
21 Court's prior order, granting summary judgment in favor of Abbott,
22 TEVA, PAR and GSK, finding insufficient evidence of proximate
23 causation with respect to Humira and 6-MP, based on the learned
24 intermediary doctrine.

25 A district court may reconsider its grant of summary judgment
26 under Federal Rule of Civil Procedure 59(e). Sch. Dist. No. 1J,
27 Multnomah County, Or. v. ACandS, Inc., 5 F.3d 1255, 1262 (9th Cir.
28 1993).

1 Plaintiffs rely on the evidence discussed above, casting
2 doubt on Dr. Rich's testimony that he was aware of the risk of
3 hepatosplenic T-cell lymphoma in late 2005, as well as testimony
4 by Dr. Rich that the Court did not discuss in its December 15,
5 2011 order. Specifically, the Court previously did not have the
6 benefit of the Rosh Report, indicating that, as of February 2005,
7 only one case report of hepatosplenic T-cell lymphoma had been
8 published, and revealing the chronology of the medical
9 publications on the risk of hepatosplenic T-cell lymphoma in
10 combination therapy. Furthermore, the Court's prior order did not
11 take full account of the ambiguities in Dr. Rich's testimony and
12 the vagueness of his memory as to when he learned of the risk of
13 hepatosplenic T-cell lymphoma. The Court reconsiders its December
14 15, 2011 order to ensure that it is supported in light of the full
15 record of evidence concerning causation in connection with the
16 three drugs at issue in this case. It would be unfair for Abbott,
17 GSK, TEVA and PAR to escape the impact of certain evidence because
18 it was only submitted in connection with Centocor and Johnson and
19 Johnson's later motion for summary judgment. The Court will not
20 issue inconsistent rulings simply because Defendants decided to
21 move for summary judgment at different times. Accordingly, the
22 Court reconsiders the merits of Abbott's, TEVA's, PAR's and GSK's
23 motions for summary judgment. Docket Nos. 177, 179, 183 and 185.

24 Those Defendants moved for summary judgment on the grounds
25 that Dr. Rich was aware early on of the risk of hepatosplenic T-
26 cell lymphoma in adolescent and young adult patients taking
27 Remicade with 6-MP. They relied on Dr. Rich's testimony that he
28 knew, as of late 2005, of the risk posed by Remicade in

1 combination with immunosuppressants like 6-MP for young patients
2 and that he considered those risks applicable to other TNF-
3 blockers, such as Humira. For the reasons explained above, there
4 is sufficient evidence to create a material dispute of fact as to
5 whether Dr. Rich, in fact, knew about the risk in late 2005.

6 Abbott, TEVA and PAR argue that the newly considered evidence
7 is not sufficient to change the outcome. They contend that the
8 Rosh Report establishes that the first case report was published
9 in February 2005 and an additional five cases were reported to the
10 FDA's AERS through May 2006. They contend that this verifies Dr.
11 Rich's testimony that he knew of the risk in late 2005, and that
12 there is nothing to contradict it. However, there is no evidence
13 indicating that Dr. Rich was apprised of cases of hepatosplenic T-
14 cell lymphoma in young patients receiving concomitant Remicade and
15 immunosuppressive therapy at the same time that they were being
16 reported to AERS. Instead, the evidence indicates that Dr. Rich
17 learned of these cases through the medical literature and the FDA
18 black box warning. When Dr. Rich testified that he may have
19 learned of two different cases from a colleague in the East Bay
20 and a colleague from Atlanta, he did not recall that those
21 conversations occurred before Maxx's diagnosis with hepatosplenic
22 T-cell lymphoma. Thus, the evidence does not require summary
23 adjudication that Dr. Rich learned of multiple cases of
24 hepatosplenic T-cell lymphoma in late 2005 and therefore that a
25 failure to warn of the risk did not cause Maxx harm.

26 Abbott, TEVA and PAR also argue that Plaintiffs cannot
27 satisfy their burden to produce evidence of causation by simply
28 challenging Dr. Rich's credibility as to when he learned about the

1 risk. Defendants contend that Plaintiffs made a strategic
2 decision not to ask Dr. Rich directly whether a different warning
3 would have caused him not to prescribe Humira or 6-MP. However,
4 Plaintiffs are not limited to proving causation by relying on
5 direct evidence. Rather, they rely on circumstantial evidence
6 comprising Dr. Rich's course of conduct. Dr. Rich's testimony
7 could support a jury finding that he did not learn of the risk of
8 hepatosplenic T-cell lymphoma caused by combining Remicade and 6-
9 MP in late 2005 but rather only in May 2006. Thereafter, he
10 informed the Plaintiffs that Humira offered a better safety
11 profile than Remicade and began prescribing Humira to Maxx on his
12 relapse in November 2006. If a jury made such a finding, it could
13 also rely on other testimony by Dr. Rich reasonably to infer that
14 his knowledge of the risk influenced his decision to prescribe
15 Humira, rather than Remicade, when Maxx relapsed in November 2006.
16 Specifically, Dr. Rich testified that his awareness in November
17 2006 of the risk of hepatosplenic T-cell lymphoma in connection
18 with Remicade and 6-MP informed his thinking about how to
19 prescribe the medications. Accordingly, a jury could infer that
20 knowledge of such a risk in connection with Humira would have
21 informed his treatment decision as to combination therapy with
22 that drug as well.

23 Plaintiffs have demonstrated that the Court's reconsideration
24 of its prior ruling is warranted and they have produced sufficient
25 evidence to raise a dispute of fact as to causation with respect
26 to Humira and 6-MP. The Court's prior order granting summary
27 judgment in favor of Abbott, TEVA and PAR is withdrawn and their
28 motions are denied.

1 GSK submitted an opposition to Plaintiffs' motion for
2 reconsideration separate from that submitted by Abbott, TEVA and
3 PAR. In its opposition GSK adopted the arguments made by the
4 three Defendants, but also argued that Plaintiffs cannot dispute
5 that it ceased distribution of its 6-MP product, marketed as
6 Purinethol, and sold its distribution rights for the product on
7 July 1, 2003, before the risk of hepatosplenic T-cell lymphoma
8 associated with 6-MP was reasonably scientifically knowable.

9 GSK first raised this issue in its March 2, 2011 motion for
10 summary judgment. Plaintiff opposed the motion arguing that it
11 was premature because further discovery was required to address
12 the motion. On April 19, 2011, Court denied the motion without
13 prejudice to allow for more discovery.

14 GSK raised the issue again in a footnote in its second motion
15 for summary judgment, which otherwise relied on the issue of
16 proximate causation. At the hearing, GSK requested that the Court
17 look back at its March 2, 2011 motion for summary judgment and
18 decide the merits of the issue. Plaintiffs have agreed to this
19 request without the need for filing a further opposition to the
20 motion. Therefore, the Court deems the motion resubmitted for
21 consideration.

22 Plaintiffs have not disputed that there were no reports to
23 AERS of hepatosplenic T-cell lymphoma associated with the use of
24 Purinethol before July 1, 2003 and no such reports were published
25 in medical or scientific literature by that date. Plaintiffs note
26 only that the case report authored by M. Thayu and other
27 researchers and published in February 2005 was received by the
28

1 journal for publication on May 18, 2003 and accepted for
2 publication on October 15, 2004.

3 To succeed on their strict liability claim against GSK,
4 Plaintiffs must produce evidence in support of its duty to warn.
5 "Drug manufacturers need only warn of risks that are actually
6 known or reasonably scientifically knowable." Carlin, 13 Cal. 4th
7 at 1117 (emphasis in original). Although, necessarily, one
8 occurrence of hepatosplenic T-cell lymphoma in connection with
9 Purinethol was known by the authors of the case report before July
10 1, 2003, Plaintiffs have not presented evidence that the risk was
11 actually known or should have been known by the scientific or
12 medical communities of which GSK is a part. GSK is correct that
13 information concerning the occurrence of hepatosplenic T-cell
14 lymphoma in connection with Purinethol was not reported to AERS or
15 discussed in the medical literature until after GSK ceased to
16 distribute the drug. Furthermore, drug manufacturers are not
17 required to warn of every conceivable adverse reaction. See id.
18 at 1114-15 (noting that FDA regulations are relevant in a common
19 law action for failure to warn and that a defendant could present
20 evidence that, consistent with FDA regulations, it was not
21 permitted to warn of the adverse effect because it was too
22 speculative). Thus, GSK cannot be held strictly liable for
23 failure to warn of the risk of hepatosplenic T-cell lymphoma
24 associated with Purinethol.

25 Likewise, Plaintiffs' negligence claim requires them to prove
26 that GSK "did not warn of a particular risk for reasons that fell
27 below the acceptable standard of care; i.e., what a reasonably
28 prudent manufacturer would have known and warned about." Id. at

1 1112. Plaintiffs have presented no evidence, expert or otherwise,
2 indicating that a reasonable manufacturer would have been in a
3 position to discover the case that Thayu and her co-authors
4 reported, prior to July 1, 2003. Thus, Plaintiffs cannot prevail
5 on their negligence claim against GSK.

6 GSK's motion for summary judgment on Plaintiffs' claims
7 against it is granted.

8 CONCLUSION

9 The Court denies Centocor and Johnson and Johnson's joint
10 motion for summary judgment. Docket No. 205. The Court grants
11 Plaintiffs' motion for reconsideration. Docket No. 220. The
12 Court's December 15, 2011 order is withdrawn and Abbott's, TEVA's
13 and PAR's motions for summary judgment based on the learned
14 intermediary doctrine are denied. Docket Nos. 177, 183 and 185.
15 However, summary judgment in favor of GSK is granted on the
16 grounds that there is insufficient evidence for a reasonable jury
17 to find that, before July 1, 2003 when it discontinued
18 distribution of Purinethol, it had a duty to warn of the risk of
19 hepatosplenic T-cell lymphoma, as it argued in its March 2, 2011
20 motion. Docket No. 179. The remaining parties shall appear for a
21 case management conference on August 8, 2012 at 2:00 pm, and shall
22 submit a joint case management statement one week prior to the
23 conference.

24 IT IS SO ORDERED.

25
26 Dated:

27 
28 CLAUDIA WILKEN
United States District Judge