Ramon Rossi Lopez (admitted *pro hac vice*)
(CA Bar No. 86361)
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
rlopez@lopezmchugh.com

Mark S. O'Connor (011029)
GALLAGHER & KENNEDY, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
Telephone: (602) 530-8000
mark.oconnor@gknet.com

Attorneys for Plaintiffs

James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
Telephone: 602.382.6000
Facsimile: 602.382.6070
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Telephone: (602) 382-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC **THE PARTIES' JOINT STATUS REPORT FOR THE MAY 3, 2017 CASE MANAGEMENT CONFERENCE**

In accordance with Paragraph G of Case Management Order No. 22 [Doc. 5007], the Parties hereby submit their Joint Status Report for the May 3, 2017 Case Management Conference.

I. Discovery

A. MDL Common Discovery

The Parties completed MDL common discovery on February 3, 2017.

The following depositions have been completed:

December 15, 2015	30(b)(6) re FDA Warning Letter
January 11, 2016	Kay Fuller
January 20, 2016	Continued 30(b)(6) re FDA Warning Letter
March 18, 2016	30(b)(6) re corporate structure
April 27, 2016	30(b)(6) re ESI systems structure
May 3, 2016	Murray Asch, M.D.
May 11, 2016	Carol Vierling
May 17, 2016	Anne Bynon
May 24, 2016	Len DeCant
June 2, 2016	John DeFord
June 9, 2016	Bret Baird
June 16, 2016	Robert DeLeon
June 17, 2016	Joe DeJohn
July 18, 2016	Abithal Raji-Kubba
July 27, 2016	Bill Little
July 27, 2016	Judy Ludwig
July 29, 2016	John Wheeler
August 9, 2016	Maureen Uebelacker
August 16, 2016	Daniel Orms
August 19, 2016	Mary Edwards
August 24, 2016	Cindi Walcott

August 30, 2016	30(b)(6) re REACH program
September 7, 2016	Steve Williamson
September 7, 2016	30(b)(6) re Sales/Marketing
September 7, 2016	Kevin Shifrin
September 16, 2016	Jack Sullivan
September 19, 2016	Brian Doherty
September 23, 2016	Holly Glass
September 29, 2016	John Van Vleet
October 11, 2016	Chris Ganser
October 18, 2016	Natalie Wong
November 3, 2016	Jack Sullivan (continued)
November 11, 2016	Robert Cortelezzi
December 6, 2016	David Peeler, M.D.
January 4, 2017	John Kaufman, M.D.
January 18, 2017	Michael Randall - 30(b)(6) Meridian/Denali
January 18, 2017	Kim Romney
January 19, 2017	Robert Carr - 30(b)(6) Key Opinion Leaders
January 20, 2017	Scott Trerotola, M.D.
January 24, 2017	Scott Randall
January 25, 2017	Gary Cohen, M.D.
January 26, 2017	Chad Modra - 30(b)(6) Failure Rate Thresholds
January 26, 2017	Anthony Venbrux, M.D.
January 30, 2017	Frank Lynch, M.D.
January 31, 2017	Mark Wilson
February 1, 2017	William Stavropoulos, M.D.
February 2, 2017	Mike Randall
February 2, 2017	Kevin Boyle

B. MDL Expert Disclosure and Discovery

Plaintiffs made their initial disclosures of expert witnesses on March 3, 2017 and their initial disclosures relating to the Meridian and Denali devices on April 7, 2017. Those disclosures included the following witnesses:

David W. Bates, M.D., MSc

Rebecca Betensky, Ph.D.

Mark J. Eisenberg, M.D.

David Garcia, M.D.

Steven M. Hertz, M.D.

Sanjeeva Kalva M.D.

David A. Kessler, M.D.

Thomas Kinney, M.D., M.S.M.E.

Robert M. McMeeking, Ph.D., NAE, FREng, FRSE, LFASME

Robert O. Ritchie, Ph.D.

Suzanne Parisian, M.D.

Anne Christine Roberts, M.D.

Michael B. Streiff, M.D.

Robert L. Vogelzang, M.D.

Defendants made their initial disclosures of expert witnesses on April 14, 2017 and their initial disclosures relating to the Meridian and Denali devices on May 12, 2017. Those disclosures included the following witnesses:

Christine L. Brauer, Ph.D.

Paul Briant, Ph.D., P.E.

Audrey A. Fasching, Ph.D., P.E.

David W. Feigal. Jr., M.D., M.P.H.

Clement J. Grassi, M.D.

Mark W. Moritz, M.D.

Christopher S. Morris, M.D.

Frederick B. Rogers, M.D., FACS

Moni Stein, M.D., FSIR

Ronald A. Thisted, Ph.D.

Donna Bea Tillman, Ph.D., M.P.A.

Rebuttal disclosures are due on May 12, 2017. The deadline for completion of expert discovery is July 14, 2017.

The Parties have begun scheduling depositions of experts and believe that they will need a short extension of the discovery deadline for expert depositions. We address this issue in Section III below.

The following depositions have been scheduled thus far:

May 9, 2017	David W. Bates, M.D., MSc
May 16, 2017	Steven M. Hertz, M.D.
May 17, 2017	Christopher S. Morris, M.D.
June 9, 2017	Robert O. Ritchie, Ph.D.
June 17, 2017	Thomas Kinney, M.D., M.S., M.E.
June 20, 2017	Sanjeeva Kalva, M.D.
June 21, 2017	David L. Garcia, M.D.
June 21, 2017	Anne Christine Roberts, M.D.
June 23, 2017	Rebecca Betensky, Ph.D.
July 6, 2017	Mark J. Eisenberg, M.D., MPH, FACC, FAHA

The Parties have agreed that the depositions will proceed with Plaintiffs' expert in a certain discipline first and Defendants' expert in the same discipline will follow within a reasonable time thereafter.

C. *Barazza* Discovery

The Parties have completed the depositions of the named plaintiffs.

The following depositions were taken:

October 19, 2016	Diane Washington
October 28, 2016	James Holt

November 10, 2016	Gregory Lester
November 16, 2016	Maria Barazza
November 30, 2016	Edward Mims
December 1, 2016	Nancy Mosher
December 6, 2016	Thomas Flournay
December 6, 2016	Delmar Lee Peck
December 15, 2016	Denise Tomlin
January 24, 2017	John Van Vleet
February 27, 2017	Linda Walker

The Parties have designated and disclosed experts regarding class certification issues, including Plaintiffs' recently designated and disclosed rebuttal expert reports.

D. Discovery Group I Discovery

The depositions of all Discovery Group 1 plaintiffs and spouse or family members have been completed. The Parties have also taken the depositions of all treating physicians allowed by CMO 21 with the exception of the implanting physician in the King case (whose deposition the Parties are still working to schedule). Plaintiffs have taken the deposition of a sales representative or supervisor in each of the Discovery Group 1 cases and completed those by April 10, 2017 in accordance with CMOs 20 and 21.

The following specific depositions have been completed:

January 25, 2017	Lisa Hyde (*Hyde*)
January 25, 2017	Mark Hyde (*Hyde*)
January 26, 2017	Justin Peterson (*Peterson*)
January 26, 2017	Lisa Peterson (*Peterson*)
January 26, 2017	Michael King (*King*)
January 26, 2017	Jessica King (*King*)
February 3, 2017	Doris Jones (*Jones*)
February 3, 2017	Alfred Jones, Sr. (*Jones*)
February 4, 2017	Joseph Mixson (*Mixon*)

February 4, 2017	Virginia Mixson (*Mixon*)
February 7, 2017	Deborah Ann Kaiser (*Kaiser*)
February 7, 2017	Brandy Ball (*Kaiser*)
February 8, 2017	Debra Mulkey (*Mulkey*)
February 8, 2017	Joshua Thompson (*Mulkey*)
February 8, 2017	Debra Ann Tinlin (*Tinlin*)
February 8, 2017	James Tinlin (*Tinlin*)
February 15, 2017	Brent Dewitt (*Dewitt*)
February 15, 2017	Providenica Dewitt (*Dewitt*)
February 16, 2017	Randy Nelson (*Nelson*)
February 16, 2017	Judy Nelson (*Nelson*)
February 20, 2017	Sherr-Una Booker (*Booker*)
February 20, 2017	Shomari Cottle (*Booker*)
February 20, 2017	Carol Kruse (*Kruse*)
February 20, 2017	Diane Bierre (*Kruse*)
March 20, 2017	Scott Karch (*Mulkey*)
March 21, 2017	Marcus D'Ayala, M.D. (*Booker*)
March 22, 2017	Salil Patel, M.D. (*Booker*)
March 22, 2017	Timothy McCowan, M.D. (*Kaiser*)
March 22, 2017	Anthony Avino, M.D. (*Jones*)
March 22, 2017	Keith Mallison (*Dewitt*)
March 23, 2017	Kirstin Nelson, M.D. (*Jones*)
March 23, 2017	Jay D. Goodman, M.D. (*Peterson*)
March 23, 2017	William Kuo, M.D. (*Hyde*)
March 24, 2017	Quazi Al-Tariq, M.D. (*Dewitt*)
March 27, 2017	Matthew Fermanich (*Hyde*)
March 27, 2017	David Shawn Fecher (*Kaiser*)
March 28, 2017	Marc Workman, M.D. (*Mulkey*)

March 28, 2017	Ronald Fewell, M.D. (*Kaiser*)
March 29, 2017	Chris Siller (*Mixon*)
March 29, 2017	Timothy Fischer (*Tinlin*)
March 31, 2017	Christopher Tinsley (*Kruse*)
April 3, 2017	Mark Hutchins, M.D. (*Kruse*)
April 3, 2017	Erin Torres Coda (*Nelson)*
April 4, 2017	Joshua Riebe, M.D. (*Tinlin*)
April 4, 2017	Shanon Smith, M.D. (*Kruse*)
April 5, 2017	John Weist, M.D. (*Peterson*)
April 5, 2017	Chad Laurich, M.D. (*Nelson*)
April 5, 2017	Roslyn Radee-Smith (*King*)
April 6, 2017	Robert Seidel, M.D. (*Nelson*)
April 6, 2017	David Henry, M.D. (*Hyde*)
April 7, 2017	Romeo Mateo, M.D. (*Dewitt*)
April 7, 2017	James Burks, M.D. (*King*)
April 7, 2017	Robert Ferrara (*Booker*)
April 7, 2017	Melanie Vilece Sussman (*Jones*)
April 10, 2017	Sandra Jean-Charles, M.D. (*Mixson*)
April 11, 2017	Roderick Tompkins, M.D. (*Mulkey*)
April 11, 2017	Anthony Goei, M.D. (*Mixson*)
April 11, 2017	Bill Edwards (*Peterson*)

II. Bellwether Group 1 Selection

In accordance with CMOs 11, 18, and 20, the Parties have made their submissions and responsive submissions to the Court regarding the selection of cases for inclusion in Bellwether Group 1. The Parties will be prepared to address their submissions and arguments in favor of those submissions at the CMC.

III. Extension of Expert Discovery Deadline to July 31, 2017

The Parties have conferred and jointly agree and request that the Court extend the deadline for completion of expert discovery through July 31, 2017. The present deadline is July 14, 2017. Based on the number of experts and issues and the coordination of both common and case-specific experts, the Parties have already commenced working with their experts to schedule depositions. A number of the experts will be deposed both in the MDL and on issues relevant to the medical-monitoring case (i.e. they have been designated in both cases and will be deposed in both cases). The Parties reasonably believe that they will need through the end of July to complete the discovery of the numerous experts in these cases. The extension will not impact any other deadlines presently in place.

The Parties will be prepared to discuss this with the Court at the CMC.

IV. Bellwether Group 1 Discovery Protocols

The Parties are in the process of negotiating a proposed form of CMO for discovery in Bellwether Group 1. Prior to the CMC, the Parties will submit an agreed proposed form of CMO or competing forms in the event that they do not agree on all contents of the order. The Parties will be prepared to discuss this issue at the CMC.

V. Defendants' Motion for Summary Judgment

In accordance with CMO 22, Defendants filed a motion for summary judgment based on preemption on March 24, 2017 and the Parties have met and conferred regarding Plaintiffs' response to the motion and need for time to prepare expert responses or to conduct other discovery. The Parties' respective positions are set forth below.

Plaintiffs' Position

A. Plaintiffs Should Be Permitted to Cross-Move for Summary Judgment on the Law Before Embarking on Expensive and Time-Consuming Discovery Necessary to Controvert Many of Bard's Proffered Facts on Support of Its Motion.

Plaintiffs have reviewed Defendants' Motion for Summary Judgment Regarding Preemption (the "Motion") and considered whether they need to take additional discovery

and seek Rule 56(d) relief in order to respond to the Motion. Bard's Motion sets forth alleged "facts" in response to which Plaintiffs would want the opportunity to provide expert testimony (which they contemplate will take place in the upcoming expert disclosure and discovery period) and to depose the witnesses on whose lengthy affidavits the Motion relies. However, rather than proceeding to a Rule 56(d) response and discovery, Plaintiffs expect that this Court can resolve the Motion as a matter of law and suggest a method that would allow the parties this opportunity without disturbing the current discovery schedule.

Bard's Motion is supported by a Statement of Facts that asserts 818 individual "facts" supported by two declarations with hundreds of underlying exhibits:

1) Declaration of Robert Carr -- contains 136 asserted facts and/or opinions, citing 128 documents (primarily communications with the FDA);

2) Declaration of John Van Vleet -- contains 86 asserted facts and/or opinion, citing 87 documents (primarily communications with the FDA).

Plaintiffs note that the testimony of these witnesses on the subjects in their affidavits was not previously disclosed and the witnesses were not deposed regarding these subjects (and Mr. Carr was not deposed at all in the MDL). Many of the alleged "facts" asserted in Bard's Statement of Facts are direct or slightly modified quotes from certain guidance documents, or consist of reports of submissions to the FDA and various communications with numerous employees of the FDA (who Plaintiffs cannot cross-examine under 21 C.F.R. § 20.1 (a-b)) spanning well over a decade.

As Plaintiffs advised the Court at the last CMC, Plaintiffs dispute many of the "facts" Bard submits and the manner in which Bard uses the facts in its Motion. Yet, this Court can and should decide preemption as a matter of law because the law on preemption is decidedly against Bard's argument here. Rather than controverting Bard's statement of 818 alleged "facts" and addressing the two affidavits on which they are based, Plaintiffs suggest a practical staged process in which Plaintiffs first present a cross-motion for summary judgment on preemption as a matter of law, even assuming all of Bard's alleged

facts are true. If the Court agrees with Plaintiffs, there will be no need for further action. However, if the Court concludes the issue cannot be decided as a matter of law against Bard accepting as true all of its allegations, Plaintiffs will respond to Bard's Separate Statement of Facts. By that time, expert discovery will be completed and Plaintiffs can determine what if any additional discovery is necessary to controvert many of Bard's statements of material fact.

This two-stage approach is appropriate for a variety of reasons. First, preemption is traditionally an issue that courts resolve as a matter of law. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Plaintiffs believe this case are not meaningfully different than those adjudicated in multiple other medical device preemption cases. If the issue of preemption can be resolved as a matter of law against Defendants accepting their version of the facts, the parties and the Court will conserve considerable time and resources. Responding to many of Bard's alleged "facts" will require Plaintiffs to elicit expert opinions showing the differences between the medical device premarket approval (PMA) process (for which claims are preempted) and the streamlined 510(k) clearance process—(for which claims are not preempted). Additionally, expert testimony will be required to explain that the FDA's process in clearing IVC filters was not out of the ordinary and that many of the "extra steps" the FDA required of Bard to secure clearance were necessitated by Bard's inadequate and incomplete submissions.

Compounding the problem, many of the documents and statements on which Bard relies have evidentiary deficiencies. Most are hearsay and contain hearsay within hearsay. Controverting many of Bard's alleged "facts" will involve evidentiary challenges. That laborious process that can be avoided if the Court resolves the issue as a matter of law. Similarly, Plaintiffs will not need to depose Mr. Carr and Mr. Van Vleet concerning the hundreds of statements attributed to them and the documents on which they rely. Demonstrative of the volume of evidence at issue is that a printout of Bard's Statement of Facts and supporting documents is tens of thousands of pages and barely fits in 35 large three-ring binders. The need to respond to all of those can be avoided by this process.

Plaintiffs suggest the following briefing schedule, without waiving their ability to later, if necessary, controvert many of the facts Bard's Motion relies upon:

Plaintiffs' Response and Cross-motion for Summary Judgment re Preemption (on legal issues ONLY):	May 26, 2017
Defendants' Response and Reply (on legal issues ONLY)	June 16, 2017
Plaintiffs' Reply re Cross-motion (on legal issues ONLY)	June 30, 2017

Should the preemption issue not resolve through this approach, the parties can complete the necessary expert and factual discovery by the current close of discovery.

B. Plaintiffs' Rule 56 Application

If the Court declines to follow Plaintiffs' proposed staged process, Plaintiffs request the Court deny Defendants' Motion outright or, at a minimum, allow Plaintiffs the opportunity to conduct the limited Rule 56(d) discovery outlined below.[1]

Bard's Motion is premised upon numerous alleged "undisputed facts" that purport to distinguish the process by which Bard secured FDA 510(k) clearance for its IV filters from a traditional 510(k) process. Based on its narrative, Bard suggests that Plaintiffs' claims are federally preempted because it claims Bard's clearance was more akin to the premarket approval (PMA) process used by the FDA for new medical devices brought to market. But many of Bard's alleged "undisputed facts" are contested, actually just conclusions and opinions (not facts), and based upon hearsay and other forms of inadmissible evidence.

[1] Plaintiffs make this application without waiving the right to oppose Defendants' motion on any grounds including, without limitation, its argument that the evidence in documents already obtained raises genuine, triable issues of material fact sufficient to defeat Defendants' Motion, or, that Defendants fail as a matter of law to carry its initial, threshold burden for purposes of summary judgment under Fed. R. Civ. P. 56 based on the numerous procedural and substantive deficiencies in its Motion.

If required to respond to Bard's Statement of Facts, Plaintiffs would be required to engage in discovery (including expert disclosures) to address: (1) the PMA and 510(k) processes; (2) "special controls" applicable to filter products and other Class II devices; (3) Bard's interactions with the FDA; (4) the actual FDA clearance process for Bard's IVC filters. Specifically, Plaintiffs will need to opportunity to complete expert disclosure and discovery, which will include these issues. Plaintiffs will also need to depose the two witnesses who provided declarations in support of Bard's SOF, Messrs. Carr and Van Vleet.

1. Legal Standard for Rule 56(D) Applications

Rule 56(d) provides a device for litigants to avoid summary judgment when there are insufficiencies in the discovery process to develop affirmative evidence to oppose a dispositive motion. *Burlington Northern Santa Fe R. Co. v. Assiniboine and Sioux Tribes of Fort Peck Reservation*, 323 F.3d 767, 773 (9th Cir. 2003). "The general principle of Rule 56(f)[2] is that 'summary judgment should be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." *Price v. Western Resources, Inc.*, 232 F.3d 779, 793 (10th Cir.2000) (quoting *Anderson v. Liberty Lobby*, 477 U.S. 242, 250 n.5, 106 S. Ct. 2505 (1986)).

Rule of Civil Procedure 56(d) provides "a device for litigants to avoid summary judgment when they have not had sufficient time to develop affirmative evidence." *Slama v. City of Madera*, 2012 WL 1067198, at *1–2 (E.D. Cal. Mar. 28, 2012)(citing *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1000 (9th Cir.2002)).

Rule 56(d) reads:

> *When Facts Are Unavailable to the Nonmovant*. If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
> (1) defer considering the motion or deny it;
> (2) allow time to obtain affidavits or declarations or to take discovery; or
> (3) issue any other appropriate order.

[2] Effective December 1, 2010, the Federal Rules of Civil Procedure were amended such that the general provisions of Rule 56(f) are now located at amended Rule 56(d).

Fed. R. Civ. Pro. 56(d).

Pursuant to Rule 56(d), this Court has the discretion to deny or continue a motion for summary judgment "if a party opposing the motion shows by affidavit that, for specified reasons, it cannot present facts essential to justify its position." *Cal. Union. Ins. Co. v. American Diversified Sav. Bank*, 914 F.2d 1271 (9th Cir.1990).

To secure Rule 56(d) relief, the "requesting party must show: (1) it has set forth in affidavit form the specific facts it hopes to elicit from further discovery; (2) the facts sought exist; [and] (3) the sought-after facts are essential to oppose summary judgment." *Family Home and Fin. Ctr., Inc. v. Fed. Home Loan Mortg. Corp.*, 525 F.3d 822, 827 (9th Cir.2008).

The party seeking relief should explain in its affidavit why those facts would preclude summary judgment. *See*, *Tatum v. City and County of San Francisco*, 441 F.3d 1090, 1100 (9th Cir. 2006); *California v. Campbell*, 138 F.3d 772, 779 (9th Cir. 1998).

2. A Rule 56(D)(2) Continuance Is Necessary Here.

a. Plaintiffs' Rule 56(d)(2) Affidavit

Plaintiffs have set forth in the form of a sworn Rule 56(d) compliant affidavit the additional facts they seek to discover to oppose Bard's Motion. Those facts consist largely of additional expert opinions and the depositions of the two Bard witnesses who provided declaration in support of Bard's Statement of Facts. As set forth in the affidavit, prior to Bard filing its Motion, there was no reason for Plaintiffs to anticipate that the discovery sought in the affidavit was necessary, and they focused their discovery effort on other areas of the case.

b. The Facts Plaintiffs Seek to Discover Exist

Plaintiffs seek to be able to disclose expert testimony and opinions regarding (1) the PMA and 510(k) processes; (2) "special controls" applicable to filter products and other Class II devices; (3) Bard's interactions with the FDA; (4) the actual FDA clearance process for Bard's IVC filters. Plaintiffs have experts who are qualified and available to provide such testimony and opinions.

Plaintiffs also seek to depose witnesses Carr and Van Vleet. Those witnesses presumably are available for depositions limited to the declarations they have authored in support of Bard's Motion.

c. The Facts Sought Are Essential to Oppose Summary Judgment

If the Court does not conclude that Bard's preemption argument fails as a matter of law, Plaintiffs will need the ability to disclose expert testimony regarding the FDA regulation activities, which will controvert the core of Bard's Motion.

Specifically, the following expert testimony will controvert the core of Bard's preemption argument:

- Regulatory processes related to the FDA's PMA process;
- Regulatory processes related to the FDA's 510(k) process, specifically as to the issues of special controls and the relevant statutory and regulatory 510(k) framework. (Def. Mot., at 17);
- That special controls and device specific "requirements" do not rise to the level of PMA and are consistent with traditional 510(k) clearance. (Def. Mot, at 18);
- IVC Filters are not unique nor is the 510(k) process for them different than "most devices brought to the market under 510(k) – even after the SMDA". *Id.*;
- Bard's actual 510(k) clearance process for the subject devices, including the extent to which FDA requests for clarification and action by Bard were not out of the ordinary and were necessitated by deficiencies in Bard's formal 510(k) submissions;
- The 510(k) clearance process does not apply differently to filters.

In addition, Plaintiffs must respond to Bard's mischaracterizations and inaccurate representations of regulatory processes, which are not factual but based on inappropriate conclusions. For example, Bard makes sweeping assertions that the MDA has been so overhauled that none of Plaintiffs' claims survive a federal preemption analysis. Mot. at

17-18. Plaintiffs should be allowed to challenge such drastic claims through expert testimony, particularly given the novelty of Bard's preemption arguments.

Additionally, Bard's Motion relies on two declarations of corporate officers that contain characterizations of regulatory documents and processes. Although Bard insisted it would not rely on expert testimony for its Motion, it has drafted its employees to stand in the shoes of expert witnesses making allegedly factual yet conclusory statements and opinions about the regulatory process. Plaintiffs are entitled to examine these witnesses on the foundation for their proffered facts and opinions. Plaintiffs anticipate that such discovery will expose the foundational and other deficiencies of Bard's alleged facts - that are not only disputed but inadmissible as evidence.

3. Rule 56(D)(1) Denial of Bard's Motion Is Also Appropriate.

Many of Bard's purported "facts" are inadmissible hearsay statements between Bard and FDA representatives. Moreover, Plaintiffs have no means of challenging Bard's characterization of these conversations. Plaintiffs can neither cross-examine nor otherwise conduct discovery directed at any employee of the FDA as to the agency's actions, inactions, processes, etc. *See* 21 C.F.R. § 20.1(a-b). In virtually every instance of communications with FDA set forth in Bard's moving papers there exists uncertainty about the factual basis upon which FDA expressed concern or requested additional information and the rationale for FDA's action that followed. Moreover, it is impossible to determine—because Plaintiffs cannot ask the FDA personnel involved—whether additional information possessed by Bard should have been produced to the FDA and what effect such concealed information would have had on the 510(k) process.

In short, Plaintiffs can neither verify the truth of the hearsay FDA statements and documents nor probe whether what Bard was asked to do as part of its 510(k) filter clearance was out of the ordinary in any respect or merely the result of Bard not being thorough or complete in its initial submissions. This is hugely prejudicial to Plaintiffs because the premise of Bard's preemption argument is that the 510(k) clearance process

for its IVC filters was more onerous and extensive than other 510(k) medical device clearances.

Moreover, even if Plaintiffs could theoretically depose current or former FDA employees with whom Bard had the communications relevant to Bard's Motion, the time and cost of such discovery would create undue and unnecessary delay in these proceedings, likely pushing the schedule for dispositive motions towards the end of the year and delaying bellwether trials until sometime in 2018.

Bard's preemption is inherently flawed because ultimately the relevance of FDA-related evidence is tenuous at best. Despite Defendants' arguments, "[u]nder the Federal Food, Drug, and Cosmetic Act, a manufacturer seeking to market a new medical device may attempt to bypass the FDA's normal premarket approval process by submitting a '§ 510(k) notification.'" *Huskey v. Ethicon, Inc.*, 848 F.3d 151, 160 (4th Cir. 2017) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996)). It is well-established that the 510(k) process only "tangentially" examines the safety of the product going through the process. *Lohr*, 518 U.S. at 493-94 ("Thus, even though the FDA may well examine § 510(k) applications for Class III devices with a concern for the safety and effectiveness of the device, it did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process.") (internal citation omitted); *Cisson v. C.R. Bard Inc. (In re C.R. Bard, Inc.)*, 810 F. 3d 919, 922 (4th Cir. 2016). That is why FDA clearance of a medical device via the 510(k) process has limited probative value and admission of such evidence risks confusing juries by creating, inter alia, a battle of experts over alleged "robustness of the 501(k) process's safety examinations" and proffering "bald assertions by the FDA" as to such compliance has been rejected as highly probative of safety. *Huskey*, 848 F.3d at 160 (citing *Cisson*, 810 F.3d at 921-22).

Defendants' Position

During the last conference, the parties, and the Court, addressed the Defendants' desire to file a motion for summary judgment premised on a preemption argument. In Case Management Order No. 22, the Court instructed the Plaintiffs to file an affidavit or declaration that complies with Rule 56(d) of the Federal Rules of Civil Procedure with this submission if they considered further factual or expert discovery necessary (Doc. 5007). Rather than make such a submission, however, the Plaintiffs have instead proposed filing their own cross motion suggesting the Court can consider the preemption issue "as a matter of law," without considering the factual support offered by the Defendants. The Defendants object to this proposal, believing that such a procedure would be unworkable, unnecessary, and a waste of resources for both the Court and the parties.

As a threshold matter, the Plaintiffs misconstrue the Defendants' past acknowledgement that the motion can be decided "as a matter of law." Bard was not suggesting the motion could be decided without an assessment of the factual history of the device. Rather, Bard was referencing the Plaintiffs' claim that expert testimony would be necessary to oppose the motion.[1] The controlling question is whether the FDA – via its regulations, its guidance documents, and its oversight activities – imposed device-specific requirements on Bard's IVC filters regarding their safety and effectiveness. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 787 (D. Ariz. 2014). That is a question of law. *See Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) (rejecting expert testimony because "whether the FDA's approval of a [device] imposes requirements on a particular device is a question of law to be determined by the Court."). Multiple courts have likewise rejected expert testimony on the legal effect of regulations

[1] Much of the discovery the Plaintiffs claim to need in order to respond to Bard's motion involves expert testimony regarding the 510(k) process, special controls, and similar issues. In effect, the Plaintiffs appear to be suggesting the right to present expert testimony concerning the legal import of the FDA's regulatory oversight of IVC filters.

or regulatory activity. *See, e.g.*, *Livingston v. Wyeth, Inc.*, No. 1:03CV00919, 2006 WL 2129794, at *6 (M.D.N.C. July 28, 2006); *United States v. Caputo*, 374 F. Supp. 2d 632, 646 (N.D. Ill. 2005); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546-47 (S.D.N.Y. 2004); *Smith v. Wyeth-Ayerst Labs., Inc.*, 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003); *Moses v. Danek Medical, Inc.*, No. CV-S-95-512PMPRLH, 1998 WL 34024164, at *3 (D. Nev. Dec. 9, 1998); *Purnell v. United States*, No. CIV. A. No. 86-4475, 1987 WL 13790, at *3 (E.D. Pa. 1987). As the Seventh Circuit succinctly noted, "[t]he only legal expert in a federal courtroom is the judge." *Caputo v. United States*, 517 F.3d 935, 942 (7th Cir. 2008).

Here, however, the Plaintiffs appear to be suggesting the motion can be decided as a matter of law because the facts need not be analyzed. Apparently, they want to file their own motion for summary judgment arguing that preemption is categorically foreclosed with a 510(k) device, arguing that "even assuming all of Bard's alleged facts are true" and "accepting [Defendants'] version of the facts," their claims are not preempted. That position is contrary to the law. Even in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the case on which the Plaintiffs rely, the deciding vote Justice Breyer noted in his concurrence that federal law "will sometimes pre-empt a state-law tort suit" even with a 510(k) device. 518 U.S. at 503. Other courts have agreed. *See Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) ("This result is entirely consistent with *Medtronic*, which did not involve device-specific federal requirements."). Accordingly, the Defendants believe a preliminary motion on the theoretical application of preemption on a 510(k) product, devoid of the factual context, would be a wasteful exercise. Instead, because the preemptive effect of the FDA's regulatory oversight does not depend simply on the regulatory pathway (PMA versus 510(k)), but rather on the special controls imposed by the agency, the specific factual circumstances of the FDA's regulatory activity will in fact be determinative of the legal issue.

Bard therefore believes the process should proceed as the Court outlined in CMO No. 22. The Plaintiffs state that they are going to file a Rule 56(d) request as

contemplated by the Court's order, but despite repeated requests, they have declined to share that request with the Defendants.[2] As a consequence, the only information available to Bard at this juncture is the generalized statements contained in this submission. Such descriptions do not satisfy the requirements for a Rule 56(d) request. An application under that provision must "make clear what information is sought and how it would preclude summary judgment." *Nicholas v. Wallenstein*, 266 F.3d 1083, 1088-89 (9th Cir. 2001). A general or conclusory assertion that additional discovery is needed – as the Plaintiffs have done here – is insufficient. *See, e.g.*, *Tatum v. City and County of San Francisco*, 441 F.3d 1090, 1100 (9th Cir. 2006) (affirming summary judgment and specifically approving district court's refusal to grant Rule 56(d) relief because non-movant "did not identify the specific facts that further discovery would have revealed or explain why those facts would have precluded summary judgment").

Nor does the Plaintiffs' description of facts they allegedly say they need – even if formalized in an affidavit – appear to be an appropriate use of the Rule 56(d) procedure. Fact discovery on the regulatory history of Bard's IVC filters took place during the year-long fact discovery period that concluded February 3, 2017. Throughout that period, the Plaintiffs had notice that preemption was an issue, since the defense was pled in Bard's master answer. (*See* Doc. 366 at Defense No. 7).[3] Also, during that period, the Plaintiffs deposed both of the declarants multiple times, Mr. Carr twice as a Rule 30(b)(6) representative and Mr. Van Vleet twice (once as a corporate representative and once as an individual). They also deposed Mary Edwards, who was a former Vice President of Regulatory Affairs (the position presently held by Mr. Van Vleet). Prior to the MDL, the Plaintiffs' co-lead counsel took a six-hour deposition of Shari Allen, another regulatory executive at the company. Additionally, they have access to the transcripts of ten other

---

[2] Because the Plaintiffs have not shared their anticipated filing with the Defendants, Bard has not been afforded a meaningful opportunity to respond. Bard therefore asks for the opportunity to respond to the details of the Rule 56(d) request once it is provided to them.

[3] Hence, contrary to Plaintiffs' assertion, they did in fact have reason to "anticipate" that the discovery they are now seeking would be necessary.

depositions taken of Mr. Carr prior to the MDL. Finally, the Plaintiffs took a 30(b)(6) deposition regarding the Meridian® and Denali® Filters, and many of the topics concerned the regulatory history of those devices.

Rule 56(d) is not applicable in these circumstances. "Rule 56(d) does not reopen discovery; rather it forestalls ruling on a motion for summary judgment in cases where discovery is still open and provides the prospect of defeating summary judgment." *Dumas v. Bangi*, No. 1:12-CV-01355-LJO, 2014 WL 3844775, at *2 (E.D. Cal. Jan 23, 2014); *accord Lexington Ins. Co. v. Scott Homes Multifamily, Inc.*, No. CV-12-02119-PHX-JAT, 2015 WL 751204, at *5 (D. Ariz. Feb 23, 2015). The rule is not a vehicle to extend discovery automatically whenever a party is faced with a summary judgment motion. Instead, it "provides a device for litigants to avoid summary judgment when they have not had sufficient time to develop affirmative evidence." *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1000 (9th Cir. 2002); *see also Roberts v. McAfee, Inc.*, 660 F.3d 1156, 1169 (9th Cir. 2011) ("[T]his rule requires discovery only where the non-moving party has not had the opportunity to discover information that is essential to its opposition." (emphasis added)); *Caravan Mobile Home Sales, Inc. v. Lehman Bros. Kuhn Loeb, Inc.*, 769 F.2d 561 (9th Cir. 1985) (affirming district court's denial of Rule 56(d) relief (formerly 56(f)) where nonmoving party had been allowed ample discovery and had taken almost 400 pages of deposition testimony from the witness whom the party sought to depose).

Finally, the Plaintiffs raise evidentiary concerns, including hearsay, regarding the affidavits and facts submitted by Bard in support of its motion. The Plaintiffs' argument is premature at this stage. The Plaintiffs are free to raise evidentiary objections to Bard's motion when they file their response brief. *See* Fed. R. Civ. Proc. 56(c)(2).

In sum, the Plaintiffs' "preview" of any Rule 56(d) declaration they may eventually file suggests that the submission would not satisfy the requirements of that provision. If the Plaintiffs want to circumvent the fact discovery deadline and expand their opportunity to conduct fact discovery beyond the year-long discovery period already afforded them,

they should be required to comply with Rule 56(d) as written and as interpreted by the Ninth Circuit.

VI. Schedule for *Daubert* Motions and Discovery Group 1 Summary Judgment Motions

In CMO 18, this Court stated that its intention was to set a schedule that would permit the completion of bellwether discovery and motion practice in time to hold the first bellwether trial in the Fall of 2017.

On the assumption that the Court agrees to the extension of the close of expert discovery to July 31, 2017, the Parties propose the following schedule for *Daubert* motions and Discovery Group 1 case-specific summary judgment motions (if any):

Daubert and summary judgment motions due:	August 21, 2017
Plaintiffs' responses due:	September 15, 2017
Reply briefs due:	September 29, 2017

VII. Plaintiffs' Proposal for a Science Day

Plaintiffs' Position:

Plaintiffs propose that the Court allow the Parties to hold a "science day" at which each side can present the Court with information from doctors, scientists, and other experts regarding Bard's IVC filters, the alleged science and medicine behind them, and the Parties' competing positions regarding the safety and efficacy of the devices and what will be at issue in the bellwether trials. Plaintiffs suggest that such a day makes sense after the completion of expert discovery and before this Court hearing and deciding *Daubert* and summary judgment motions.

Plaintiffs disagree with Defendants' suggested time limits. Because there are multiple devices and design/complication issues, Plaintiffs submit that 75-90 minutes per side is more appropriate.

Defendants' Position:

The Defendants will be happy to participate in a "science day" if the Court believes the exercise will be beneficial. From past experience, the Defendants believe 45-60

minute presentations by both sides (perhaps made in conjunction with a regularly scheduled case management conference) are the most efficient means of accomplishing the aims of a "science day."

VIII. Timing of Remand of Mature Cases

Plaintiffs' Position:

Plaintiffs request that the Court address the timing of remand of the mature cases when it determines the schedule for briefing and resolution of *Daubert* issues. As the Court noted in CMO 19, it will handle common expert disclosures and *Daubert* motions for those experts. However, once this Court has made any such rulings, those cases will be ready for remand. Plaintiffs would like to include the timing of the remand of the mature case in the schedule relating to the *Daubert* motions and resolution of the other common matters in this MDL.

Once the Court renders its ruling on *Daubert* motions, this Court will remand the ten cases that have been identified as "mature/early remand cases" to the transferor courts for further pre-trial and trial proceedings, and the parties will be able to use the new fact and expert discovery taken in this MDL.

Defendants' Position:

This same issue was raised by the Plaintiffs at the last case management conference, and addressed by the Court in Case Management Order No. 19 [Doc 4311]. As the Plaintiffs acknowledge, the Court is going to handle common expert disclosures and *Daubert* motions in the context of this MDL. Once the Court issues rulings in *Daubert* motions, the parties and the Court can discuss a procedure for the prompt remand of the cases. However, the Defendants do not see how a more specific schedule can be established at this juncture, since the timing of any remands will be linked to the date of the Court's ruling on *Daubert* motions, and that date cannot be determined in advance.

IX. Motion to Disqualify One Plaintiffs' Expert

The defendants have recently filed a motion to disqualify one of the plaintiffs' experts, Dr. Thomas Kinney. The motion is premised on (1) the fact that Dr. Kinney

previously consulted with the defendants as an expert witness in filter cases, and (2) the fact that Dr. Kinney consulted with Bard Peripheral Vascular, Inc. for a number of years on a wide variety of filter-related projects, including animal testing of prototype devices, physician training, and the analysis of complication data. The defendants maintain that Dr. Kinney had access to confidential data and litigation strategies as a result of that work, and in fact was a signatory to various confidentiality agreements.

Plaintiffs have consulted and discussed with Dr. Kinney his prior association with Bard and both Dr. Kinney and Plaintiffs have concluded that prior affiliation, some ten years ago, did not expose Dr. Kinney to information that would disqualify him in this lawsuit or that there is any conflict created by the report and opinions he has issued in this suit. Plaintiffs will respond to Defendants' motion.

X. Expert Discovery in Barazza

Defendants' Position

The Plaintiffs designated their rebuttal experts in the *Barazza* putative class action on Friday, April 21st. The following Monday (April 24th), Bard promptly requested deposition dates for one of the newly disclosed experts (Dr. Kush R. Desai) to be completed prior to the May 19th deadline for all discovery in the Barazza case. Despite multiple follow-up inquiries by Bard (given the short time frame available), the Plaintiffs have not responded. Bard is becoming concerned about completing discovery by the deadline if Plaintiffs delay any further in providing a date for that deposition.

Plaintiffs' Position

Plaintiffs have been working diligently to schedule the depositions of numerous experts, including Dr. Desai. Plaintiffs will continue to work to schedule these depositions timely and are working to obtain dates from Dr. Desai. Plaintiffs have not received dates for Defendants' experts' depositions in the MDL or for the *Barazza* case but do not believe it is necessary to take up this Court's time with individual deposition scheduling issues.

Respectfully submitted this 28th day of April 2017.

GALLAGHER & KENNEDY, P.A.

By: *s/ Paul L. Stoller*
Mark S. O'Connor (011029)
2575 East Camelback Road
Phoenix, Arizona 85016-9225

Ramon Rossi Lopez
(admitted *pro hac vice*)
CA Bar No. 86361
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Attorneys for Plaintiffs

SNELL & WILMER L.L.P.

By: *s/ Richard B. North*
James R. Condo
Amanda C. Sheridan
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
Nelson Mullins Riley & Scarborough LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363

Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April. 28, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Deborah Yanazzo