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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

)
In Re: Baycol Product Litigation) MDL No. 1431 MJD
)
) 9:30 a.m. o'clock
) February 6, 2003
) Minneapolis, MN
)
) VOLUME I
)

BEFORE THE HONORABLE MICHAEL J. DAVIS
UNITED STATES DISTRICT COURT JUDGE
(CLASS CERTIFICATION HEARING)

APPEARANCES:

ON BEHALF OF THE PLAINTIFF: CHARLES ZIMMERMAN, ESQ.
ARTHUR MILLER, ESQ.
ELIZABETH CABRASER, ESQ.
STANLEY CHESLEY, ESQ.
RICHARD ARSENAULT, ESQ.
RICHARD LOCKRIDGE, ESQ.
JOHN CLIMACO, ESQ.
DIANNE NAST, ESQ.

ON BEHALF OF THE DEFENDANT: PHILIP BECK, ESQ.
PETER SIPKINS, ESQ.
SUSAN WEBER, ESQ.
FRED MAGAZINER, ESQ.
ADAM HOEFLICH, ESQ.
REBECCA BACON, ESQ.

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1 THE CLERK: Multi-District Litigation No. 1431, 09:34:37

2 In re: Baycol Products. Please state your appearances for 09:34:41

3 the record. 09:34:44

4 MR. ZIMMERMAN: Good morning, Your Honor, Charles 09:34:45

5 Zimmerman for the Plaintiffs Steering Committee. 09:34:46

6 THE COURT: Good morning. 09:34:50

7 MR. CHESLEY: Good morning, Stanley Chesley for 09:34:53

8 the Plaintiffs Steering Committee. 09:34:55

9 THE COURT: Good morning. 09:34:57

10 MS. CABRASER: Good morning, Elizabeth Cabraser 09:34:58

11 for the Plaintiffs. 09:35:01

12 THE COURT: Good morning. 09:35:02

13 PROFESSOR MILLER: Good morning, Arthur Miller 09:35:04

14 for the Plaintiffs. 09:35:06

15 THE COURT: Good morning, Professor. 09:35:08

16 MS. NAST: Dianne Nast for the Plaintiffs. 09:35:12

17 MR. CLIMACO: John Climaco, Plaintiffs Steering 09:35:15

18 Committee. 09:35:20

19 MR. ARSENAULT: Richards Arsenault for the 09:35:20

20 Plaintiffs Steering Committee. 09:35:23

21 THE COURT: Good morning. Mr. Beck. 09:35:25

22 MR. BECK: Philip Beck for the Defendants, and I 09:35:27

23 want to introduce, also, if I may, Dr. Roland Hartwig who 09:35:30

24 is the General Counsel from Bayer AG who is here this 09:35:37

25 morning. 09:35:42

1 THE COURT: Good morning. 09:35:43

2 MR. BECK: Also Gary McConnell, Senior Counsel 09:35:46

3 for the Bayer United States, and with me are my colleagues 09:35:51

4 from my firm Rebecca Weinstein Baker and Allison Freedman. 09:35:53

5 THE COURT: Good morning. 09:36:01

6 MS. WEBER: Good morning, Susan Weber for Bayer, 09:36:02

7 and I have a couple of my colleagues, James Mizgala and 09:36:05

8 Sherry Knutson.

9 THE COURT: Good morning. 09:36:13

10 MR. BECK: I'm sorry, one of my late arriving 09:36:15

11 colleagues who hasn't worked very hard on this matter is 09:36:19

12 Adam Hoeflich. 09:36:24

13 THE COURT: You got him on the hard bench back 09:36:26

14 there. What did you do to deserve that, Adam? 09:36:28

15 MR. HOEFLICH: I lost a motion the last time, 09:36:34

16 Judge. 09:36:37

17 MR. MAGAZINER: Fred Magaziner for 09:36:38

18 GlaxoSmithKline. 09:36:43

19 MR. SIPKINS: Peter Sipkins. 09:36:48

20 MR. SCHAERR: Gene Schaerr for Bayer. 09:36:51

21 THE COURT: Good morning. Mr. Zimmerman. 09:36:52

22 MR. ZIMMERMAN: May it please the Court, Counsel, 09:37:16

23 about a year ago, Your Honor, I made a pledge to this Court 09:37:26

24 and the PSC made a pledge, and that was to do justice. The 09:37:29

25 Plaintiffs and Defendants in April in New Orleans made a 09:37:37

1 pledge to the courts around the country and lawyers around 09:37:43
2 the country to do justice. A pledge of fair, equal and 09:37:46
3 inexpensive justice. 09:37:54

4 Today in this courtroom we seek fair, fast, equal 09:37:57
5 and inexpensive justice. What is justice? What is fair? 09:38:03
6 Fast, inexpensive justice. According to the Supreme Court, 09:38:09
7 it's the touchstone of federal procedure. It is stated as 09:38:13
8 the purpose of the federal rules in Rule 1 to be 09:38:19
9 administered to secure just, speedy and inexpensive 09:38:24
10 determinations of every action. 09:38:28

11 The concept of justice, however, is not a static 09:38:32
12 one. In 1969, Justice Thurgood Marshall at the Tenth 09:38:37
13 Annual James Madison series said justice must be revised to 09:38:47
14 suit the times. 09:38:52

15 Today, Your Honor, we are at a crossroads. 09:38:54
16 Decisions we make today will be affecting everyone in this 09:38:58
17 country with the Baycol case. Everyone looking to this MDL 09:39:01
18 for help in this litigation, everyone looking to this MDL 09:39:10
19 for management and resolution of the issues that will 09:39:15
20 advance their claim. And, really, everyone who looks to 09:39:17
21 the federal courts for answers to complex legal problems. 09:39:25

22 This MDL, the Baycol litigation, involves one 09:39:28
23 product, Baycol, one manufacturer, Bayer, who in a period 09:39:32
24 of less than 42 months injured thousands and thousands of 09:39:39
25 people with one signature disease. 09:39:44

1 The question really is how are we going to fairly 09:39:48
2 and promptly compensate the victims who truly deserve 09:39:54
3 compensation and fairly treat people who deserve medical 09:40:04
4 monitoring. How are we going to fairly administer justice, 09:40:07
5 give equal justice to all? To make our system work to 09:40:11
6 those with legitimate claims, and I mean legitimate claims, 09:40:15
7 and do so again without unreasonable delay, without 09:40:18
8 unneeded expense, and without unneeded repetition of the 09:40:23
9 litigation. 09:40:26

10 How are we going to resolve common issues and 09:40:29
11 prevent endless relitigation of the same issues for far as 09:40:34
12 the eye can see. And, Your Honor, we have choices -- 09:40:39
13 choices that will be guided by experience and the law. 09:40:43
14 Experience, Your Honor, we are fortunate, we are very 09:40:50
15 fortunate. Almost every major mass tort decision after 09:40:53
16 every major mass tort case in this country over the last 15 09:40:57
17 years have been litigated by lawyers in this courtroom 09:41:02
18 today -- breast implants, tobacco, diet drugs, Albuterol, 09:41:06
19 Telectronics, asbestos, Ford, Firestone, Propulcid, 09:41:13
20 Rezulin, Sulzer. All of the lawyers that were the 09:41:19
21 architects and Steering Committee of those cases are here 09:41:24
22 today. And all cases cited, or almost all cases cited by 09:41:27
23 both parties in the brief that involve these issues, we 09:41:31
24 have the people here who can compare and contrast and 09:41:36
25 discuss in a learned way with this Court those decisions. 09:41:41

1 Those facts must be well understood and the law must be 09:41:45
2 well understood. 09:41:49

3 We have Professor Arthur Miller. He brings to us 09:41:50
4 an extreme range of understanding and experience. I 09:41:56
5 believe he will demonstrate to this court how and why a 09:42:00
6 class action is superior, how and why a class action can 09:42:04
7 work and be managed and show how and why a well-managed 09:42:08
8 class action is not only possible but practical, and will 09:42:15
9 serve the interest of effective management of this MDL. 09:42:22

10 And we will show how and why a well-managed class 09:42:27
11 action can resolve issues common to all Baycol litigants, 09:42:33
12 plaintiff and defendant. And then we will hear from 09:42:37
13 Elizabeth Cabraser as well who will demonstrate to us why a 09:42:41
14 refund class to be certified before this court is the right 09:42:46
15 thing to do. 09:42:51

16 Your Honor, you will hear sharp contrast. 09:42:53
17 Plaintiffs will show the possibilities. Defendants will 09:42:58
18 attempt to show the reasons why not. We call it the parade 09:43:02
19 of horrors. Defendants will try and show why thousands and 09:43:05
20 thousands of cases and thousands of trials in ever federal 09:43:10
21 district in this country is best when again we have one 09:43:16
22 drug, one manufacturer, one set of liability facts in a 09:43:19
23 period of 42 months who were given to a universe of people 09:43:24
24 with the same problem, high cholesterol, and produced the 09:43:33
25 same signature disease. They are going to demonstrate to 09:43:37

1 this Court how justice should be piecemealed and delayed. 09:43:40

2 But, Your Honor, the ultimate discretion in the 09:43:45

3 final analysis lies with Your Honor. Much discretion under 09:43:49

4 the federal rules is vested in this Court. 09:43:55

5 The Court will hear learned debate. I trust the 09:43:59

6 debate will be vigorous and the debate will be learned and 09:44:04

7 the debate honorable. But in the end, after all is said 09:44:09

8 and the dust is settled, I believe there will be little 09:44:13

9 doubt that justice will be best served, fairness best 09:44:16

10 administered, our pledges best kept by this Court's proper 09:44:20

11 management of a class. We hope Plaintiffs' argument and we 09:44:25

12 believe Plaintiffs' argument will be disciplined, linear 09:44:34

13 and persuasive. 09:44:36

14 My job is to introduce Professor Miller and 09:44:40

15 Elizabeth Cabraser who will argue the law. First, we'll 09:44:45

16 hear from Richard Arsenault for the factual predicate that 09:44:50

17 has to be laid out so the Court will understand how the 09:44:55

18 issues are common and how the issues can be managed. 09:45:01

19 Then we'll ask the Court to address any questions 09:45:04

20 to the Steering Committee, and we're all here to answer 09:45:06

21 them. We hope our cumulative experience will be a benefit 09:45:11

22 to the Court. We are each here and prepared to answer 09:45:16

23 questions. So, I would like to begin. But I would like to 09:45:19

24 leave the Court with one thought before I sit down. 09:45:22

25 I'd like to paraphrase the words of Bobby Kennedy 09:45:25

1 who said many times in many parts of the country, "Some men 09:45:28

2 see things that are and say why. I dream things that never 09:45:37

3 were and say why not." 09:45:43

4 I ask this Court to see the possibilities, the 09:45:48

5 potential, the promise, that justice can be given to all 09:45:48

6 who look to this Court for fast, fair and inexpensive 09:45:54

7 justice by utilizing the superior methods of Rule 23. 09:46:00

8 Thank you. 09:46:07

9 At this time I would like to introduce Richard 09:46:10

10 Arsenault. 09:46:13

11 THE COURT: Thank you, Mr. Zimmerman. 09:46:17

12 MR. ARSENAULT: Good morning, Your Honor. 09:46:19

13 Richard Arsenault for the Plaintiffs Steering Committee. 09:46:20

14 Your Honor, we think the facts in this case 09:46:28

15 demonstrate, in this litigation, essentially, involve a 09:46:31

16 single product, a single marketing campaign, and single set 09:46:31

17 of scientific issues. The key themes present the following 09:46:36

18 common issues. 09:46:40

19 The Defendants' studies were improperly used to 09:46:41

20 market Baycol. Evidence of this will apply in all cases. 09:46:44

21 The Defendants manipulated adverse events, data. 09:46:50

22 This conduct, likewise, applies to all cases. At any dose, 09:46:55

23 Your Honor, with or without concomitant use, Baycol created 09:46:57

24 more than twice the risk of any other statin. At any dose, 09:47:03

25 Baycol was unreasonably dangerous. It simply lacked the 09:47:07

1 efficacy and did not justify the risks presented. 09:47:12

2 The Plaintiffs' evidence about the injuries 09:47:15

3 caused by Baycol is the same in every case, myalgia, 09:47:19

4 myopathy, rhabdomyolysis. They are all conditions caused

5 by the same mechanism. The differences are just 09:47:26

6 differences in the degree of muscle deterioration and 09:47:29

7 kidney involvement. 09:47:33

8 If individual cases are tried separately, courts 09:47:34

9 will have to hear the same evidence, the same testimony 09:47:37

10 over and over again. 09:47:42

11 Statins, Your Honor, are used to treat, rather, 09:47:45

12 high cholesterol. Whether the Defendants in this case 09:47:50

13 decided to enter the statin market, there were already five 09:47:53

14 statins on the market. Those were Mevacor, Zocor, 09:47:57

15 Pravachol, Lescol and Lipitor. These statins are still on 09:48:01

16 the market today, whereas Baycol was withdrawn in August of 09:48:06

17 2001. During its short life span, some 900,000 patients 09:48:10

18 used Baycol. Over 4,000,000 prescriptions were written, 09:48:16

19 and some 25,000,000 free sample packets were distributed. 09:48:20

20 The statin market is a rather lucrative one. In 09:48:26

21 1999 the U.S. market was growing by nearly 40 percent. The 09:48:32

22 sales for '97 projected to reach 4,000,000,000, rising to 09:48:38

23 9,000,000,000 by 2001. 09:48:42

24 Statins had been on the market for over a decade 09:48:44

25 without Baycol. The existing variety and number of statins 09:48:48

1 adequately covered the waterfront. Nevertheless, the 09:48:52
2 Defendants hoped to squeeze into the statin-growing 09:48:55
3 multi-billion dollar sector. 09:49:00

4 Your Honor, Baycol was created in Germany in the 09:49:02
5 late '90s -- late '80s rather. In 1991 Bayer AG offered 09:49:05
6 Bayer U.S. an opportunity to participate in Baycol's 09:49:14
7 development and commercialization. This offer, however, 09:49:14
8 was met with resistance by Bayer U.S. Dr. Lawrence Posner, 09:49:16
9 who is worldwide head of Regulatory Affairs for Bayer, and 09:49:22
10 Dr. Gerald Rosenberg, who is the Senior Vice President of 09:49:26
11 Sales and Marketing, they both recommended against Baycol's 09:49:29
12 development in the United States. We have a passage here 09:49:33
13 from Dr. Rosenberg that explains what he refers to as his 09:49:36
14 bosses in Germany had to say. Doctor Rosenberg explains -- 09:49:41
15 and Professor Meyer and other senior management in Germany 09:49:45
16 said, "We know what you're saying, but we disagree with 09:49:48
17 you. We want you to develop this." And Rosenberg goes on 09:49:52
18 to say, "They are the bosses, so we agreed to go through 09:49:58
19 with the development." 09:50:02

20 He was then asked, "So they could override the 09:50:03
21 decision not to do it made by you and Dr. Posner?" He 09:50:08
22 answered, "Absolutely." "And Professor Meyer, what was his 09:50:11
23 title with Bayer AG?" "He was the head of the 09:50:14
24 pharmaceutical business group worldwide, the most senior 09:50:18
25 individual in pharmaceutical on a worldwide basis." 09:50:22

1 Now, GSK, like Bayer AG, also wanted in on this 09:50:27
2 statin market. Initially, GSK promoted Zocor, one of the 09:50:34
3 other statins. However, that contract came to an end when 09:50:39
4 GSK was accused of not meeting their contractual 09:50:41
5 obligations. GSK then moved to another statin, or at least 09:50:45
6 tried to, and that was Lipitor, and had not able to get 09:50:50
7 that contract. They finally settled on Baycol, signing a 09:50:52
8 co-promotional agreement with Bayer on July 21, 1997. 09:50:58
9 However, their involvement was turbulent from the very 09:51:03
10 start. 09:51:07

11 Your Honor, even before the co-promotional 09:51:08
12 agreement was signed, GSK was painfully aware of Baycol's 09:51:12
13 safety and efficacy problems. In a June 1997 letter, 09:51:16
14 nearly one month prior to the signing of the co-promotional 09:51:23
15 agreement, Jerry Karabelas, who was the GSK Vice President, 09:51:29
16 wrote David Ebsworth, Bayer's Pharmaceutical President 09:51:29
17 about these problems. 09:51:33

18 This is -- these are passages from the June of 09:51:42
19 1997 correspondence, Judge. Karabelas says, "The message 09:51:49
20 was simple and safe, simple price, simple dosing, milligram 09:51:54
21 efficacy at microgram doses. No worry about drug 09:52:00
22 interactions. This was a product with a profile we were 09:52:04
23 excited to market. One that we believed offered excellent 09:52:09
24 income opportunities to both Bayer and GSK." He goes on to 09:52:13
25 explain, "Now, more than a year after working with these 09:52:20

1 original assumptions and developing sales forecasts, we 09:52:22
2 have learned more about Baycol. And in light of these 09:52:25
3 changes, the opportunity is not as we expected." And, 09:52:28
4 again, this is one month before they enter into the 09:52:32
5 co-promotional agreement. 09:52:34

6 He goes on to conclude, "In summary, the profile 09:52:37
7 of Baycol has now evolved to one of low cost, comparable 09:52:39
8 efficacy to Lescol," that's one of the other statins, "with 09:52:46
9 drug interaction that could be magnified at higher doses. 09:52:46
10 Simple and safe no longer appears to be a viable 09:52:54
11 promotional platform." Now, this is a company that's going 09:52:57
12 to be co-promoting Baycol, and this is a month before they 09:53:00
13 signed that agreement. 09:53:06

14 GSK was also aware that increased dosage would be 09:53:08
15 critical for Baycol to compete. That's is why they want 09:53:14
16 major force and the development of the .4 dose. In fact, 09:53:16
17 Your Honor, the co-promotional agreement contained a 09:53:18
18 specific provision which allowed GSK to terminate the 09:53:21
19 agreement if .4 was not approved for marketing by August 1, 09:53:26
20 1999. Dr. Rosenberg was asked and explained why did that 09:53:32
21 provision end up in the co-promotional agreement. He 09:53:37
22 answered, "I think that provision was in there because GSK 09:53:42
23 felt to be competitive in this marketplace we had to have a 09:53:45
24 product that would reduce cholesterol at a higher level 09:53:48
25 than we were able to get in the .2 and the .3 doses. 09:53:54

1 Therefore, they wanted the 4 doses to be available. They 09:53:57
2 knew they needed a stronger dose to be competitive, but 09:54:02
3 they also knew that as the dose increased, there was a 09:54:03
4 commensurate increase in the danger. 09:54:06

5 How do you market a product like this? We have 09:54:09
6 some documents that suggest how the marketing took place. 09:54:14
7 The Defendants made conscious decisions to stretch the 09:54:19
8 data, to push regulatory authorities to the limit and skew 09:54:22
9 studies for marketing purposes. What we have here were 09:54:27
10 excerpts from minutes from the September 30, 1998 Baycol 09:54:32
11 grand review meeting and they spell it out. We need to 09:54:36
12 stretch the data to the maximum. Other companies have 09:54:41
13 developed an attitude of pushing marketing material 09:54:46
14 aggressively, following the philosophy, we do not know 09:54:50
15 where the legal boundary is until we hit it. 09:54:53

16 One may not value this, but since it is the rule 09:54:56
17 in the market, we as a company have to follow it. The area 09:55:00
18 is greater than we treat it. We can pick the better study 09:55:04
19 for the detail aid. It is the role of marketing to 09:55:10
20 challenge regulatory systematically. 09:55:11

21 It didn't take long, however, for this data 09:55:18
22 stretching to catch up with the Defendants. In October of 09:55:21
23 1999, the FDA's Division of Drugs, Marketing, Advertising 09:55:26
24 and Communications cited Bayer's promotional materials as 09:55:30
25 false, lacking in fair balance, or otherwise misleading. 09:55:35

1 What we have here, Your Honor, is excerpts from 09:55:43
2 is that letter. On the first page it notes references made 09:55:43
3 to the sales aid submitted under cover of form FDA 2253, 09:55:57
4 dissemination of this material by Bayer Corporation and/or 09:56:03
5 Bayer agents violates the Federal Food, Drug and Cosmetic 09:56:06
6 Act. 09:56:11

7 It goes through the aid and talks about some of 09:56:12
8 the representations the Defendants were making. The sales 09:56:17
9 aid, for example, in their discussion about the science for 09:56:20
10 success, the FDA said that the presentation under this 09:56:24
11 header is misleading because it implies without substantial 09:56:27
12 evidence that Baycol is superior. 09:56:31

13 On the second page there is discussion about 09:56:35
14 claims that were being made by Bayer about Baycol being a 09:56:39
15 powerful enzyme inhibition. The FDA concluded, again, the 09:56:43
16 presentation under this header is misleading because it 09:56:49
17 implies that Baycol is superior. Apparently, Bayer was 09:56:53
18 also making claims that there were dramatic results across 09:56:57
19 key lipid parameters. Likewise, the FDA concluded that the 09:57:01
20 presentation of HDL-C efficacy information under this 09:57:06
21 header was misleading because it overstated the efficacy of 09:57:07
22 Baycol. 09:57:13

23 There were claims being made with regard to 09:57:14
24 Baycol that it was proven significantly better than 09:57:17
25 Pravachol, one of the other statins. The FDA concluded 09:57:22

1 that the presentation under this header is misleading 09:57:25

2 because it implies that Baycol is superior to Pravachol 09:57:29

3 without substantial evidence. 09:57:31

4 The FDA concluded that the promotional materials 09:57:33

5 lacked fair balance. They exploded the presentation of 09:57:37

6 risk information in this promotional piece lacks fair 09:57:42

7 balance. Promotional materials may be lacking in fair 09:57:43

8 balance or otherwise misleading if they fail to present 09:57:46

9 information relating to side effects and contraindications 09:57:48

10 with a prominence and readable reasonable comparable to the 09:57:53

11 presentation of efficacy information. 09:57:58

12 The FDA admonished that Bayer should immediately 09:58:00

13 cease using this and all other promotional materials for 09:58:06

14 Baycol that contained the same or similar violations. 09:58:11

15 There is a concept in this case, Your Honor, that 09:58:17

16 deals with concomitant use and throughout the facts you'll 09:58:22

17 be hearing terms like monotherapy and concomitant use. 09:58:25

18 Statins, as you know, is a drug helps that lower 09:58:31

19 cholesterol. Many people who have high cholesterol also 09:58:34

20 have high triglyceride levels. The cholesterol is treated 09:58:40

21 with a statin, and Baycol is one of those statins. The 09:58:43

22 triglyceride situation is treated with fibrates. One of 09:58:47

23 the popular fibrates is Gemfibrozil. So, when we talk 09:58:50

24 about the terms concomitant use, we are typically talking 09:58:53

25 about the use Baycol and Gemfibrozil together. When we are 09:58:56

1 talking about monotherapy, we are talking about Baycol 09:58:59
2 being used alone. 09:59:04
3 Your Honor, in this case, the Defendants knew 09:59:06
4 from the beginning that the Baycol was dangerous. As early 09:59:09
5 as May, 1999, they knew that when compared to other 09:59:13
6 statins, Baycol presented a much greater risk of 09:59:17
7 rhabdomyolysis. In fact, 5 to 10 times more with 09:59:22
8 monotherapy and 100 to 200 times more with concomitant use. 09:59:26
9 There are five sources -- at least five sources that stand 09:59:32
10 for this proposition that we have cited in an illustrative 09:59:36
11 sense. 09:59:40
12 Baycol was sold in the U.K. under the trade name 09:59:40
13 Lipobay. What you see next is a slide by Dr. Tim Shannon 09:59:45
14 who's making a presentation to the FDA's equivalent in 09:59:52
15 England, June 21, 2001 presentation. And as you can see at 09:59:57
16 the top there, November of 2000, they are talking about 10:00:03
17 Lipobay which is, again, the trade name in England. And in 10:00:08
18 those comparisons the rhabdomyolysis risk profile with 10:00:12
19 other statins in freedom of information database shows 10:00:14
20 difference for monotherapy five to tenfold and combination 10:00:17
21 therapy one hundred fold. 10:00:22
22 During Baycol's three and a half year life span 10:00:33
23 in the U.S., it was marketed to the public in four 10:00:33
24 different doses, those being .2, .3, .4, and .8. 10:00:36
25 Initially, Bayer sought approval of even smaller dosages, 10:00:41

1 .05 and .1. However, when Baycol was actually launched in 10:00:50
2 the U.S., only the .2 and the .3 were initially marketed. 10:00:54

3 From its inception, Baycol was plagued with
4 efficacy problems. Early on the FDA informed Bayer the
5 absolute efficacy of this drug at these doses is limited
6 relative to other market statins. And this comes from a 10:01:10
7 1997 FDA medical review memo. Because of these efficacy 10:01:14
8 problems, approval for higher doses was constantly sought. 10:01:23
9 However, again, as the dosages increased, the danger 10:01:26
10 increased. Notwithstanding the risk, the Defendants moved 10:01:30
11 to a .4 dose and then a .8 dose. They considered a 1.6 and 10:01:34
12 a 3.2 dose, and those clinical trials presented such 10:01:40
13 obvious and serious problems at these levels that Bayer 10:01:43
14 abandoned the development of those doses. 10:01:47

15 Again, as the Defendants increased dosage, they 10:01:51
16 exponentially increased the dangerous side effects of this 10:01:56
17 drug. An increase of enzymes called CK or CPK are 10:01:57
18 indicators diagnostic of the rhabdomyolysis problem. 10:02:04

19 As early as 1999, Bayer expressed concern about 10:02:07
20 CPK elevations. In fact, minutes of a July 21, 1999 video 10:02:14
21 conference revealed that it is not acceptable to study 1.6 10:02:18
22 because of the high incidence of CK elevation and an 10:02:23
23 exponential increase in side effects from .8 to 1.6 doses. 10:02:30
24 Development of the 3.2 is likewise not recommended for 10:02:32
25 similar reasons. 10:02:37

1 The Defendants flooded the market with .8 10:02:40
2 samples, and what we are going to do now is just go through 10:02:42
3 four or five, maybe half a dozen vignettes that illustrate 10:02:48
4 some common issues and conduct that's applicable to every 10:02:51
5 Baycol case. 10:02:54

6 Why the Defendants admonished that .8 was not to 10:03:01
7 be a starting dose, they inexplicably gave away millions of 10:03:01
8 .8 samples. These samples were distributed with such 10:03:10
9 enthusiasm, that as of March 2001, the samples outnumbered 10:03:14
10 .8 prescriptions 2 to 1. In fact, .8 samples were 10:03:18
11 distributed to sales reps even before the FDA approved .8. 10:03:22
12 In June of 2000, a conference called took place with key 10:03:28
13 Bayer executives. The discussions included a patient 10:03:33
14 information leaflet that warned about increase 10:03:36
15 rhabdomyolysis risks associated with Baycol use. 10:03:36

16 The executives all agreed that the leaflets 10:03:41
17 should be prepared before July 12, 2000, and that was the 10:03:45
18 date that the FDA was scheduled to meet regarding the .8 10:03:48
19 approval. The executives decided, and this is in the memo, 10:03:55
20 this leaflet should not be distributed prior to .8 Baycol 10:03:59
21 approval, otherwise, most likely it will delay the 10:04:03
22 approval. 10:04:07

23 Again, this is illustrative of the priorities 10:04:10
24 that Bayer had with regard to this drug. There was some 10:04:14
25 that opposed the .8 launch, and we have an example of that. 10:04:18

1 Bayer moved forward with this .8 launch despite 10:04:24
2 those of the organization that knew it was ill-advised. 10:04:30
3 Dr. Richard Goodstein was the Bayer VP of Scientific 10:04:35
4 Relations. We are starting to see stress, Your Honor, 10:04:38
5 between the scientific part of Bayer and marketing part of 10:04:40
6 Bayer. In any event, Dr. Goodstein recognized the danger, 10:04:45
7 expressed his opinion and found himself as what he referred 10:04:51
8 to as a minority of one. His exchange with fellow Bayer 10:04:53
9 employee, Pat Stenger, and she was the Bayer Internal 10:04:58
10 Manager of Scientific Affairs, two science people here, the 10:05:01
11 exchange takes place on May 13, 2000 following a Baycol 10:05:05
12 project team meeting. 10:05:10
13 He writes Pat and says, "Thank for your report 10:05:13
14 below. I am indebted for your inside information or I 10:05:18
15 would not have the latest news." He goes on to say, The 10:05:22
16 status of things does not surprise me. I see a false 10:05:25
17 comfort factor in place across the company for obvious 10:05:30
18 reasons. It appears the strategy is to get by the July 10:05:34
19 hurdle," and that was the .8 launch hurdle date, "and 10:05:40
20 continue to be silent. I will know more when I meet with 10:05:44
21 Karen Dawes face to face on Monday and with Neil and Felix. 10:05:46
22 Unfortunately, I think that unless the OL," and those were 10:05:52
23 opinion leaders, so, that would be the opinion leader 10:05:57
24 meeting, "takes place on May 19, and they push hard as we 10:06:00
25 have, for immediate response, we will not see any specifics 10:06:04

1 until after launch," and that is after the .8 launch. "This 10:06:09
2 message seems very clear given the total lack of response 10:06:18
3 to my note two weeks ago that the subject is in control of 10:06:18
4 global drug safely now, and they will respond per Worldwide 10:06:23
5 Marketing. We are a minority of one and have been told to 10:06:27
6 stay away upon severe penalties. We may face some tough 10:06:32
7 personal decisions as this progresses." 10:06:38

8 In an August 7, 2000 memorandum from Laurie 10:06:41
9 Simpson who was Bayer's marketing department to Tig Conger, 10:06:47
10 who is also in Bayer marketing, it becomes abundantly clear 10:06:49
11 that initially Bayer stressed the lack of problems 10:06:52
12 associated with the concomitant therapy, the therapy with 10:06:55
13 Gemfibrozil. The memo that we are going to refer to here 10:07:00
14 has a specific section called mixed messages. The memo 10:07:03
15 specifically notes and criticizes an October 1, 1999 10:07:08
16 promotional piece which should have but did not warn about 10:07:10
17 Baycol use with Gemfibrozil being contraindicated. 10:07:15

18 And if you can go to the second page that's up 10:07:21
19 there, Your Honor, you can see under Baycol there's a mixed 10:07:23
20 message and a question mark. And it says initial marketing 10:07:28
21 stressed, a no drug/drug interactions, and apparently the 10:07:32
22 theme there is mixed messages. Well, you see a little 10:07:35
23 lower down on the document it says, awareness of contra 10:07:40
24 indication and physician reaction. 10:07:42

25 So, if we send mixed messages, what do we expect 10:07:45

1 to occur? The answer is right here. It says during 10:07:49
2 marketing research, some physicians have spontaneously 10:07:54
3 mentioned the contraindication. Reactions were mixed. So, 10:07:57
4 when you send mixed messages, you get mixed reactions. 10:08:02
5 Reactions were mixed from highly negative, i.e., one more 10:08:04
6 reason not to use Baycol to neutral. All statins have this 10:08:08
7 warning. Statins are safe and it's no big deal. 10:08:13

8 A few more examples, Your Honor, of how Bayer was 10:08:21
9 trying to react to the adverse events and the activity that 10:08:26
10 they were seeing with this drug actually on the market. 10:08:31
11 This section gives you some examples of how they were 10:08:35
12 trying to inappropriately blame it on the concomitant use. 10:08:38

13 They knew there was a problem with the use of 10:08:43
14 Baycol alone, the monotherapy. And Karen Dawes who is the 10:08:45
15 Bayer Marketing Senior Vice President admitted it. She 10:08:51
16 testified that the majority, over 60 percent of the 10:08:53
17 rhabdomyolysis from launch to the point where they put in 10:08:57
18 the contraindication for Gemfibrozil in December, 1999, 10:09:01
19 those were caused by the use of Baycol alone, monotherapy. 10:09:05
20 So, here she's admitting that 60 percent of the problems 10:09:10
21 are caused under circumstances where Baycol is being used 10:09:13
22 by itself. 10:09:15

23 Notwithstanding that, in December of 1999, Bayer 10:09:17
24 sends a letter to health care professionals across the 10:09:21
25 United States with input from the Bayer GSK Steering 10:09:26

1 Committee describing the Gemfibrozil contraindication 10:09:35
2 change in the package insert stating that the majority of 10:09:35
3 the rhabdomyolysis was caused by Baycol with Gemfibrozil. 10:09:37
4 Ms. Dawes was deposed and she indicated while no 10:09:43
5 cases of rhabdomyolysis were reported, this is an exhibit 10:09:49
6 during her deposition, while no cases of rhabdomyolysis
7 were reported during the extensive clinical trials of 10:09:52
8 Baycol, there had been a number of cases reported during 10:09:57
9 the post-marketing period. Now, here she takes the 10:10:00
10 position the majority of which patients taking -- excuse 10:10:06
11 me, the majority of which involved patients taking 10:10:10
12 concomitant Baycol and Gemfibrozil. 10:10:10
13 Incredibly, even though Bayer knew that most of 10:10:16
14 the problems were occurring with monotherapy, it told its 10:10:19
15 sales force that in the majority of cases, Rhabdo was 10:10:22
16 occurring where Baycol was being us concomitantly. 10:10:25
17 Even at the time of Baycol's withdrawal, sales 10:10:31
18 reps were being shown data showing the safety issues with 10:10:31
19 Baycol resulted primarily from concomitant use. 10:10:34
20 Another strategy was to try to blame it on class 10:10:40
21 effect. Class effect, essentially, is when there is a 10:10:45
22 similar group of drugs the position is that they all have 10:10:46
23 the same problem. But finding Gemfibrozil 10:10:50
24 contraindication, the defense tried to minimize the problem
25 by arguing this class effect, i.e., all statins have this

1 problem. However, they knew the problem was Baycol 10:11:00
2 specific. There was something about Baycol that made it 10:11:03
3 different when it was combined with Gemfibrozil. 10:11:06
4 What you see now is an e-mail from Richard King, 10:11:10
5 who is with GSK Marketing to David Rand, who is a GSK 10:11:18
6 Marketing Senior VP. It's dated January 24, 2000, and 10:11:22
7 acknowledges that there was something specific about Baycol 10:11:24
8 which created the concomitant use problems. He notes, 10:11:27
9 "Gemfib is not a drug interaction, but is a quirky 10:11:34
10 interaction with Baycol." 10:11:38
11 Now, what were Baycol's quirks? How was it 10:11:40
12 different from the other statins? Well, number one, it was 10:11:45
13 up to one hundred times more potent than any other statin. 10:11:50
14 Number 2, other statins used one metabolic pathway. Baycol 10:11:55
15 used two. Baycol alone caused rhabdomyolysis 5 to 10 times 10:12:05
16 more than any other statin. Baycol in combination with 10:12:11
17 Gemfib caused Rhabdo 100 to 200 times more often than any 10:12:13
18 other statin, and this is even though Baycol only had a 10:12:19
19 small percentage of the market share. 10:12:20
20 Baycol caused the highest body burden event of 10:12:21
21 any statin due to metabolization problems. Unlike other 10:12:25
22 statins, Baycol had no study proving it lowered morbidity 10:12:30
23 or mortality, and Baycol was at least twice as likely to 10:12:36
24 cause myopathies as any other statin on the market. 10:12:42
25 In discovery, Your Honor, we have also seen 10:12:48

1 distortions that took place by sales representatives at the 10:12:50
2 behest of these defendants. Sales representatives were 10:12:53
3 instructed to minimize the impact of information delivered 10:12:57
4 to doctors regarding the label changes, i.e., the 10:13:01
5 contraindications Baycol with Gemfib. In a written memo to 10:13:03
6 sales reps, Bayer told reps not to unduly prolong 10:13:06
7 physicians with the label change. 10:13:15

8 On December 3, 1999 Bayer instructed its sales 10:13:15
9 force not to emphasize important safety information when 10:13:18
10 meeting with doctors. Specifically, Bayer issued a letter 10:13:21
11 and a scripted Q and A, question and answer to a sales
12 force regarding the label change and contraindication. 10:13:27
13 Included with the instructions was the statement, please do 10:13:29
14 not unduly alarm physicians with regard to this label 10:13:32
15 change by starting your presentation with this issue. 10:13:37

16 A scripted Q and A was also provided for 10:13:40
17 addressing physicians' inquiries and instructed sales reps 10:13:44
18 not to answer questions which were not addressed in the Q 10:13:50
19 and A. 10:13:52

20 A March 2000 feedback from the field memo quotes 10:13:54
21 numerous sales representations commenting that they were 10:14:01
22 told not to bring up the Baycol-Gemfib contraindication. 10:14:01

23 Similar internal documents recommend that the 10:14:09
24 sales rep stress that the label change was for patients' 10:14:10
25 safety and that sales rep should not acknowledge the number 10:14:10

1 of adverse events. Rather, Bayer instructed the sales rep 10:14:14
2 to emphasize the anticipated .8 approval that was upcoming 10:14:20
3 in July of 2000. 10:14:23

4 I've got another example here of some promotional 10:14:27
5 materials, Your Honor. The first one is what's called a 10:14:30
6 promotional version. Bayer recognized that safety required 10:14:33
7 .8 -- the .8 dose to be titrated. You didn't started at 10:14:39
8 .8, you worked your way up, .3, .4 titration does. 10:14:43
9 However, Bayer mislead doctors as to this critical dosing 10:14:49
10 information. Bayer directed its sales force to use a 10:14:53
11 promotional version. And this is a promotional version 10:14:57
12 here. We're going to show you the journal in a moment.

13 But Bayer directed its sales force to use a promotional 10:15:03
14 version of its exciting tug boat ad when making calls on 10:15:05
15 doctors. 10:15:07

16 While the promoted version characterized .8 as a 10:15:12
17 powerful titration dose, it contained no safety 10:15:12
18 information, including language recommending .4 as a 10:15:17
19 starting dosage. At the same time, Bayer published a tug 10:15:19
20 boat ad in 2001 issues of the American Heart Association 10:15:23
21 Journal. The .4 milligram dose was characterized as an 10:15:30
22 effective starting does while the .8 was characterized as 10:15:32
23 even more power when you need it. The ad contained a 10:15:36
24 legend recommending .4 as a starting dose and other safety 10:15:43
25 information. 10:15:44

1 If you go back to the promotional version, 10:15:45
2 please, the promotional version had doctors for the curious 10:15:48
3 legend for representative consultant use only, not to be 10:15:50
4 left with the physician. Bayer's sales representatives 10:15:57
5 were instructed never to leave the promotional version with 10:16:00
6 physicians. Bayer didn't want the physicians to compare 10:16:05
7 the ads in question prescribing .8. 10:16:09

8 The Defendants told sales representatives not to 10:16:11
9 discuss the U.K. withdrawal. This drug was withdrawn in 10:16:16
10 England before it was withdrawn in the United States. 10:16:19
11 Bayer continued its don't tell philosophy in 2001. 10:16:19

12 Shortly before the market withdrawal in the U.K., 10:16:24
13 Karen Dawes, who was the Senior VP of Sales and Marketing, 10:16:26
14 forwarded a message and scripted Q and A to the sales force 10:16:29
15 regarding withdrawal to .8 in the U.K. Bayer explicitly 10:16:36
16 instructed its sales force not to initiate discussions with 10:16:43
17 the U.S. physicians regarding the U.K. withdrawal. 10:16:43

18 THE COURT: What was the date of the U.K. 10:16:45
19 withdrawal? 10:16:47

20 MR. ARSENAULT: It as shortly before that, Your 10:16:48
21 Honor. I don't know the exact date -- June 27th. 10:16:52

22 In June 2001, Bayer employee Mitch Druell, 10:17:06
23 Director of Scientific Affairs, forwarded an e-mail to a 10:17:11
24 sales training manager with similar instructions not to 10:17:15
25 discuss the U.K. situation, specifically, the memo noting, 10:17:18

1 "You will find comments from the field forces to use if a 10:17:21
2 physician asks about Baycol in the U.K. Please reinforce 10:17:23
3 the sales representatives should not initiate this 10:17:28
4 discussion. Please forward this message to your teams." 10:17:32
5 Your Honor, the discovery also revealed that the 10:17:35
6 defendants manipulated clinical trials and the data 10:17:38
7 associated with that. In a variety of marketing materials 10:17:42
8 and detail aids, Bayer touted Baycol safety and claimed 10:17:46
9 that no one developed Rhabdo in the clinical trials. 10:17:51
10 However, Bayer never informed the health care providers 10:17:57
11 that it pulled patients from clinical studies before they 10:18:00
12 reached full-blown rhabdomyolysis. An example of this 10:18:03
13 appears in a memorandum dated March 11, 1999 from Lori 10:18:07
14 Simpson who is the Marketing Research Manager to the Baycol 10:18:10
15 project team. She specifically notes, "in clinical trials, 10:18:14
16 patients are typically closely monitored and would be 10:18:18
17 discontinued prior to reaching Rhabdo. 10:18:22
18 The Defendants also manipulated the definition of 10:18:26
19 rhabdomyolysis. They were getting these adverse events on 10:18:29
20 a regular basis, and depending on how you manipulated the 10:18:35
21 definition, that would impact the number of hits that you 10:18:41
22 were getting in terms of adverse events coupled with 10:18:43
23 rhabdomyolysis. 10:18:43
24 What follows is a memo, Your Honor, from Roger 10:18:47
25 Celesk, he's the Associate Director of Safety Assurance at 10:18:50

1 Bayer, to Kuno Sprenger, a member Global Drug Safety. It's 10:18:52
2 illustrative of many documents and sworn testimony which is 10:18:57
3 established that Bayer manipulated the Rhabdo definition 10:19:04
4 with the obvious goal of attempting to cosmetically reduce 10:19:06
5 reports of rhabdomyolysis. The Rhabdo definition from 10:19:18
6 Global Drug Safety is a moving target. Amazingly, Roger 10:19:21
7 Celesk, who at this time is the Association Director of 10:19:29
8 Safety Assurance, doesn't even know what the definition GDS 10:19:29
9 is using. 10:19:35

10 He notes, "there may have been a shift in the GDS 10:19:41
11 attitude regarding what we call Rhabdo. So that I may 10:19:44
12 clarify this issue for myself and colleagues in West Haven, 10:19:48
13 Connecticut, could you provide the formal definition GDS 10:19:51
14 now uses to create a diagnosis of Rhabdo when it is not a 10:19:58
15 reported term. Thanks for your help." 10:20:01

16 The Defendants also either ignore or sometimes 10:20:06
17 undermine the studies that were adverse to Baycol. A June 10:20:08
18 22, 1999 internal sales training bulletin summarized the 10:20:13
19 results of a study comparing Lipitor with Baycol. The 10:20:18
20 study concluded that only 5 percent of the Lipitor group 10:20:24
21 experienced adverse events, whereas, a 14 percent of Baycol 10:20:27
22 did. Additionally, two percent of the Baycol withdrew from 10:20:35
23 the study due to adverse events. There were no Lipitor 10:20:35
24 withdrawals. 10:20:40

25 The study concluded that Lipitor demonstrated a 10:20:40

1 significantly better tolerability profile compared to 10:20:47
2 Baycol. Despite these conclusions, the training bulletin 10:20:48
3 outlined a counter strategy sales representatives should 10:20:54
4 use, if confronted with questions regarding this study, but 10:20:56
5 admonished the sales reps not to leave the information with 10:21:02
6 doctors or a related e-mail advised, we should not use the 10:21:04
7 study or the argument against the design of this trial 10:21:08
8 proactively. This statement is only aimed to help argue in 10:21:09
9 the case that some doctor may raise the issue. Bayer 10:21:14
10 conveyed the message to its sales representatives to not 10:21:18
11 initiate these discussions. 10:21:22

12 Eventually, the drug was withdrawn and that took 10:21:23
13 place on August 2001 following meetings with the FDA in 10:21:27
14 July or August of that year where the FDA expressed grave 10:21:34
15 reservations about Baycol's safety, particularly the high 10:21:39
16 rates of Rhabdo and myopathy, in both combination and 10:21:41
17 monotherapy. 10:21:45

18 The data gathered each year from 1998 to 2001 10:21:46
19 showed that the incidence of fatal rhabdomyolysis reported 10:21:53
20 to the FDA was up to eighty times higher among patients 10:21:57
21 using Baycol and than among patients using other statins. 10:22:02

22 The actual decision to withdraw Baycol came just 10:22:06
23 five days after a critical August 3, 2001 FDA letter to 10:22:11
24 Bayer requesting that Bayer update its drug application of 10:22:13
25 Baycol by submitting all the safety information currently 10:22:17

1 in Bayer's possession. Furthermore, the FDA specifically 10:22:21
2 asked for all data, regardless of dose level. 10:22:25
3 Additionally, they asked for a re-tabulation of the reasons 10:22:30
4 for premature study discontinuation. Rather than give up 10:22:34
5 this information that would confirm the FDA's grave 10:22:40
6 reservations, Bayer finally withdrew Baycol. 10:22:45

7 I wanted to speak just for a moment, Your Honor, 10:22:48
8 with regard to the medical monitoring claim. At the end of 10:22:51
9 the day, the medical monitoring relief sought essentially 10:22:54
10 presents three simple questions that have universal 10:23:00
11 applicability and present common issues. 10:23:03

12 Number one, do we need it? Number two, will it 10:23:08
13 help? Number three, who will pay? 10:23:09

14 Many patients exposed to Baycol suffered 10:23:15
15 significant and ongoing loss of kidney function. This 10:23:19
16 creates a risk for silently progressive kidney disease, 10:23:25
17 including the risk of kidney failure. If detected, the 10:23:28
18 disease can be treated and further injury and/or death can 10:23:32
19 be avoided. 10:23:35

20 According Dr. Kaysen, a world-renown 10:23:36
21 nephrologist, it's generally accepted in the field of 10:23:40
22 nephrology that patients who suffer from an impaired kidney 10:23:43
23 function should receive medical monitoring to detect and 10:23:46
24 treat progressive renal disease. The process by which 10:23:50
25 Baycol causes Rhabdo often goes undiagnosed, and in turn 10:23:55

1 causes injury to the kidneys which continues to go
2 undetected.
3 Medical monitoring is necessary to ensure that 10:24:00
4 loss of kidney function or damage to the kidneys do not go 10:24:05
5 undiagnosed and untreated, thereby placing the patients at 10:24:09
6 risk for further harm. Dr. Kaysen recommends a simple 10:24:15
7 periodic blood test to measure serum creatinine and blood 10:24:19
8 pressure monitoring. When renal function is impaired, it's 10:24:23
9 indicated by an elevated serum creatinine test. National
10 guidelines for monitoring and treatment can be found.

11 Science and related literature supporting Dr. 10:24:32
12 Kaysen's report to this court establishes beyond dispute 10:24:37
13 that simple, expensive serum creatinine testing will in 10:24:41
14 fact provide early detection of potential serious problems. 10:24:46

15 Based upon Dr. Kaysen's report the common 10:24:51
16 questions are these, Your Honor. Whether medical 10:24:54
17 monitoring is necessary to detect and prevent silent and 10:24:57
18 progressive harm due to Baycol use. And if so, what is a 10:25:01
19 reasonable plan for medical monitoring and should the 10:25:05
20 Defendants bear the cost of monitoring? And these 10:25:09
21 questions have global applicability to everyone who would 10:25:12
22 potentially be a class member available for this remedy. 10:25:16

23 At the end of the day, Your Honor, both Bayer US 10:25:21
24 and ASK were correctly apprehensive about bringing Baycol 10:25:24
25 to the United States. They knew about the efficacy 10:25:30

1 problems at that would require the constant dosage 10:25:35
2 increases. They also knew that if they increased the dose, 10:25:38
3 they unreasonably increased the risk. Their plan, as we've 10:25:42
4 seen, was to stretch the data and push regulatory 10:25:46
5 authorities to the limit, pick the better study for the 10:25:51
6 detail aid, push the legal boundary until they hit it. 10:25:52
7 Eventually, they did hit and exceeded it. 10:25:57

8 In the meantime, as we've seen, they did a lot of 10:26:02
9 bobbing and weaving. Constant dosage increases, blaming it 10:26:05
10 on concomitant use, blaming it on class effect, using the 10:26:09
11 sales representatives as buffers, hiding information from 10:26:13
12 the health care providers, manipulating definitions, 10:26:15
13 manipulating the data, flooding the market with samples, 10:26:22
14 withholding critical safety information, sending mixed 10:26:22
15 messages, and undermining or ignoring adverse studies. 10:26:26
16 Eventually, no tactics could keep this drug afloat and it 10:26:29
17 was withdrawn. 10:26:35

18 Your Honor, what we have here are an illustrative 10:26:36
19 list, and I'm not going to go through all of them. They 10:26:40
20 are in your bench book. They are illustrative. There are
21 25 different issues that give you a sense for what are some 10:26:42
22 of the common issues in this particular case. 10:26:46

23 We also have a time line that because of time 10:26:49
24 constraints I'm not going to go into very much detail, but 10:26:53
25 it outlines in a lot of detail what Bayer knew and at the 10:26:57

1 same time what they were saying. I appreciate your time. 10:27:03

2 THE COURT: Thank you. Let's take a stretch 10:27:11

3 break. Mr. Zimmerman. 10:27:11

4 MR. ZIMMERMAN: Thank you, Your Honor. Next, I'm 10:36:47

5 going to introduce Mr. Arthur Miller with the next 10:36:49

6 argument. 10:36:56

7 THE COURT: You had made some comments in your 10:36:56

8 opening remarks, and I don't want to interrupt Professor 10:37:00

9 Miller when he gives his or Mr. Beck when he responds, but 10:37:07

10 one of the things that concerns the Court, and I don't ask 10:37:15

11 a lot of questions during oral arguments, so, don't be 10:37:18

12 surprised if I don't ask any because I've read all the 10:37:23

13 materials and I try to digest everything. 10:37:28

14 One of the things that was clear in my mind is 10:37:34

15 that you want class certification, but you don't know how 10:37:37

16 to get together if it's on the trial end of it. You say 10:37:51

17 that you have a lot of people here from all these different 10:38:00

18 types of litigations across the country. Certainly to say 10:38:04

19 that the materials that I received did not give a cogent 10:38:10

20 view of how a trial would proceed. And I have 20 years of 10:38:22

21 being on the bench and being a trial attorney. It's one 10:38:28

22 thing to win a motion, but you've got to give a judge 10:38:35

23 direction on how that case is going to be tried, just not 10:38:41

24 to say you won, let's fly. 10:38:45

25 It takes a lot of effort and direction, and in 10:38:48

1 dealing with that, and I think defense has certainly dealt 10:38:56
2 with that issue, and I'm sure Mr. Beck will deal with that 10:38:59
3 issue again when he argues or whoever is going to be 10:39:07
4 arguing for the defense, and that's one of the points that 10:39:10
5 the Plaintiff has. 10:39:13

6 I start in what do you want me to do and how do 10:39:17
7 you want me to do it, and you have not given me any visual 10:39:23
8 help on how that would happen other than with the mass 10:39:29
9 confusion. 10:39:34

10 So, I put that out so you can map with your 10:39:46
11 people how you want to deal with that. But that's going to 10:39:51
12 have to be dealt with. And if you don't deal with it, 10:39:56
13 that's one of my major concerns. I have some other major 10:40:00
14 concerns that you will address, and Professor Miller and 10:40:06
15 Mr. Beck will address those issues. But the weakest point 10:40:08
16 of the presentation and materials that I have seen, it's 10:40:14
17 one of those, hey, we won, now, let's go ahead and try to 10:40:18
18 put it together. And I think the Defendants say even if 10:40:24
19 they win, they can't put it together, and you are going to 10:40:28
20 have to address those issues. 10:40:32

21 MR. ZIMMERMAN: I appreciate that, Your Honor, 10:40:36
22 and I submit to you that we will and we should and we must. 10:40:36

23 THE COURT: Okay. 10:40:39

24 MR. ZIMMERMAN: And I appreciate that. 10:40:40

25 THE COURT: Just as long as at some point and 10:40:42

1 time -- I know you have down here rebuttal. 10:40:50

2 MR. ZIMMERMAN: With that question in mind, I ask 10:40:57

3 that Mr. Miller come before you and show how a well-managed 10:40:59

4 class action can resolve a common issues to aid in the just 10:41:05

5 and fair and appropriate resolution of the case for all 10:41:10

6 claimants as well as for all Defendants. Mr. Miller. 10:41:14

7 THE COURT good morning. 10:41:25

8 MR. MILLER: Good morning, may it please the 10:41:29

9 Court, you've on the bench 20 years and been a trial lawyer 10:41:31

10 for 10 years before that. I've been in academic for 40 10:41:39

11 years, never tried a case, so in a curious way this is a 10:41:46

12 slight mismatch. Mr. Beck, who I have un-unqualified 10:41:56

13 regard for, has, of course, that experience. We have 10:42:04

14 Elizabeth Cabraser who is a distinguished complex 10:42:06

15 litigation trial attorney. 10:42:14

16 What I'd like to do is set it up in response to 10:42:15

17 your question. But do it, I suppose, the way academics do 10:42:21

18 things by wandering around a little bit. 10:42:26

19 When I was walking over here this morning, being 10:42:30

20 led by some very attractive seeing eye dogs -- 10:42:35

21 THE COURT: I hope you went through the skyways. 10:42:40

22 MR. MILLER: Through the skyways, I said to 10:42:44

23 myself, the metaphor is things change, a great Don Ameche 10:42:49

24 movie. 10:42:58

25 I was here 40-odd years ago on the U's law 10:43:00

1 faculty, and the only building of consequence was the 10:43:04
2 Foshay Tower. And no matter which range they took me over, 10:43:08
3 I looked for the Foshay Tower, and I couldn't see it. 10:43:13
4 THE COURT: And there was only one or two 10:43:17
5 bridges. 10:43:21
6 MR. MILLER: I believe there was one, maybe two, 10:43:22
7 things change, things change. 10:43:25
8 When federal Rule 23 was drafted as we now know 10:43:27
9 it in '63, effective '66, there were really no complex 10:43:30
10 cases. Judicial management was unknown. Federal Rule 16 10:43:38
11 envisioned nothing but an eve of trial conference. And no 10:43:44
12 one who drafted federal Rule 23, and I was one of them, 10:43:50
13 working with the then reporter while I was still in 10:43:56
14 practice and then when I was here at the U, no one 10:44:00
15 envisioned anything like what we have today. Yes, we 10:44:05
16 envisioned desegregation cases. We envisioned some 10:44:10
17 securities case and some anti-trust cases. 10:44:16
18 Mr. Zimmerman said in his opening remarks, you 10:44:18
19 have to change with the times. You have to have 10:44:24
20 flexibility, elasticity, you have to be wise. The beauty 10:44:31
21 of the Federal Rules of Civil Procedure is that it was 10:44:35
22 drafted initially and sequentially by very wise people, 10:44:42
23 people who saw the value of open he textured rules that 10:44:44
24 could be elastic when needed to be. 10:44:50
25 And the Bench changes. In the Advisory Committee 10:44:59

1 Rule with the 66th Amendment, there is a little passage 10:45:04
2 that says, ordinarily, doesn't say never, ordinarily, the 10:45:12
3 rule shouldn't be used in mass accident cases. I was 10:45:17
4 wracking my brain as to whether I wrote that the Ben Kaplan 10:45:22
5 the reported, which means I gave birth to artifact. It's 10:45:30
6 dead. Nobody refers to that anymore. Everybody 10:45:33
7 understands that was the product of that time and the 10:45:36
8 political pressures within the committee and outside the 10:45:39
9 committee working on the committee. Nobody mentions it 10:45:44
10 anymore. 10:45:48
11 Rule 16, a whisper in 1983 began to bark, began 10:45:50
12 to speak loud terms. Began to speak about management, 10:45:55
13 building on the manual which had no official status, the 10:46:03
14 electrical supply cases, and, obviously, the growth of what 10:46:08
15 we now call complex cases. 10:46:11
16 '83, that's only 20 years ago. The first time 10:46:15
17 the word settlement appears in the Federal Rules of Civil 10:46:19
18 Procedure, first time. Reinforced in '93, reinforced in 10:46:24
19 '93. Mr. Zimmerman read parts of Rule 1 to you. 10:46:31
20 Rule 1 was amended in '93. They, the rules shall 10:46:38
21 be construed and administered, words and administered were 10:46:48
22 added in '93, and the Advisory Committee note to the '93 10:46:55
23 amendment says this, the purpose of this revision, adding 10:47:02
24 the words "and administered" to the second sentence is to 10:47:05
25 recognize, everybody knew it. Very often things get 10:47:09

1 codified into the rules, and to recognize the affirmative 10:47:15
2 duty of the court to exercise the authority conferred by 10:47:19
3 these rules to ensure that civil litigation is resolved not 10:47:25
4 only fairly, but also without undue cost or delay. 10:47:30
5 And here's a sentence that I suppose speaks to 10:47:37
6 Mr. Beck and speaks to my colleagues, speaks to me. As 10:47:41
7 officers of the court, attorneys share this responsibility 10:47:46
8 with the judge to whom the case assigned. The affirmative 10:47:50
9 duty to administer. Speed, fair, cost. 10:47:57
10 Now, in this forty-year spread, we have seen the 10:48:06
11 emergence of the complex case, the mass case, the 10:48:11
12 aggravated case, the class action. And life is pendular, 10:48:17
13 goes back and forth. We've gone through cycles. We've 10:48:24
14 loved the class action, we've hated the class action. And 10:48:28
15 then we fell in love with it again. Maybe we don't quite 10:48:33
16 love it as much today. Cycles, cycles. 10:48:37
17 Indeed, there is almost a religious debate 10:48:45
18 between the proponents and opponents of the class action. 10:48:49
19 The proponents, using their brand of hyperbole, say, oh, 10:48:55
20 it's a panacea. I remember a great, great district judge, 10:49:03
21 Chief Judge of Missouri, primary author of the manual, Bill 10:49:05
22 Becker, used the old panacea, panacea, a tool of social 10:49:13
23 justice. And we know in a variety of context such as 10:49:18
24 reapportionment, desegregation, some form of 10:49:22
25 discrimination. It has been a tool of social justice. 10:49:25

1 It's a field leveler. It's an access mechanism. It gives 10:49:31
2 distributive of justice. 10:49:36
3 There is hyperbole on the other side. It's been 10:49:38
4 called the Frankenstein monster. It's been called 10:49:43
5 extortion. It's been called a bunch of lawyer cases. The 10:49:49
6 truth, obviously, lies somewhere off those extremes. But 10:49:53
7 with all these cycles back and forth, there has been one 10:50:00
8 constant, and nobody has given up on it. We have just 10:50:06
9 gotten more sophisticated in using it. We know so much 10:50:10
10 more each day. We develop new techniques. We know how to 10:50:15
11 describe classes now. We don't say all poor people. We 10:50:25
12 know how to subclass now. We know how to write notices 10:50:30
13 now. We know how to make intelligent estimates as to the 10:50:38
14 fairness, the reasonableness and the adequacy of a 10:50:44
15 settlement. And, of course, we understand the degree to 10:50:49
16 which we have developed better calibration techniques for 10:50:56
17 attorney's fees. We've gotten smarter and smarter and 10:51:02
18 smarter. We've changed with the times. With each 10:51:07
19 challenge comes a response. 10:51:12
20 Now, here we are in 2003. We may be on the eve 10:51:15
21 of legislation that in effect pushes most large-scale class 10:51:26
22 actions into federal court. We have already had a 10:51:33
23 multi-party, multi-forum statute that came in on cat-like 10:51:39
24 feet in November attached to an appropriations bill. 10:51:42
25 Now, the Plaintiffs would be foolish if they said 10:51:47

1 to Your Honor everything is okay in River City. It's not 10:51:53
2 from their perspective. We can't deny that in the recent 10:52:00
3 past there have been a series of decisions, that explicitly 10:52:04
4 or implicitly are negative about the class action. We know 10:52:13
5 about Roland Polank. We know about Castano. We know about 10:52:23
6 AMS. We know about Bridgestone-Firestone. Indeed, many of 10:52:29
7 the people in this room were involved in those cases, 10:52:36
8 argued them and lost them. 10:52:39

9 We know about Propulcid, PPA, Rezulin, but that's 10:52:43
10 not the universe. That is not the universe. Nor do any of 10:52:50
11 those cases say thou shalt not certify. 10:52:56

12 There is another side to the ledger. Even in the 10:53:08
13 Fifth Circuit, which gave us Castano, you have Mullen, a 10:53:13
14 mass tort case, somewhat limited dimension, to be sure. 10:53:19
15 You have Watson, a single event mass tort. So, even in the 10:53:26
16 Fifth Circuit, mass tort actions do get certified. 10:53:30

17 In the Sixth Circuit which gave birth to AMS, you 10:53:43
18 still have those, a course of conduct mass tort which was 10:53:47
19 certified. Not overruled, indeed, relied on periodically 10:53:55
20 by other courts. 10:53:58

21 In the Third Circuit, you recently had the 10:53:59
22 approval of diet drugs, a case that I think we would 10:54:03
23 suggest to you has a certain similarity to this case and 10:54:10
24 provides certain footprints to answer some of your concerns 10:54:17
25 about how do you do it, how do you do it. 10:54:20

1 The Second Circuit and the Ninth Circuit, Second 10:54:23
2 Circuit in Robinson, the Ninth Circuit in Hanford Building 10:54:30
3 on Valentino versus Carter-Wallace seem open to mass tort 10:54:36
4 cases. And what's particularly interesting for purposes of 10:54:44
5 today's discussion is that both of those courts looked 10:54:49
6 forward and not backward. Both of those courts say, maybe 10:54:55
7 you should start thinking about 23(c)(4)(a), a provision of 10:54:58
8 the federal rules that's been rather quiet for 40 years. 10:55:08

9 In other words, do you get the feeling that the 10:55:14
10 Second and the Ninth Circuits recognize the pressure, the 10:55:15
11 challenges, the problems confronted by mass events. And 10:55:19
12 that's what we are talking about, whether it's a mass event 10:55:24
13 in terms of Watson with an explosion or mass event in terms 10:55:28
14 of a drug or a diet drug. Maybe we just got to be more 10:55:31
15 careful, more precise. Maybe we got to go to the toolbox 10:55:38
16 again to see what's in there that we haven't used. 10:55:43

17 So, look at that universe, Second Circuit, Third 10:55:46
18 Circuit, Fourth Circuit. Fourth Circuit in the A.H. 10:55:52
19 Robbins Bankruptcy used the class form. And then in 10:55:58
20 Central Wesleyan, also seemed quite receptive to mass class 10:56:01
21 actions. So, you've got the Second speaking, the Third 10:56:16
22 acting, the Fourth acting, the Fifth and Sixth ambivalent 10:56:16
23 going both ways. Seventh, no doubt where they stand at 10:56:22
24 this time, and the Ninth being open. 10:56:28

25 Now, what does this tell us? I think it tells us 10:56:32

1 what we have already known, that this is a matter of 10:56:39

2 judicial discretion. There are no rights or wrongs, 10:56:46
3 really. It is discretion. Some of the Judges recently, 10:56:50
4 like in Rezulin and PPA and Propulcid have exercised 10:56:57
5 negative discretion. They have. They are not binding on 10:57:03
6 this Court. Indeed, none of the cases I've mentioned are 10:57:09
7 binding on this Court. We are in the Eighth Circuit. It 10:57:14
8 hasn't spoken yet. 10:57:19

9 So, there is discretion. And how do you exercise 10:57:21
10 that discretion? We say in context, in context. 10:57:25

11 None of the cases in which class certification 10:57:34
12 has been denied match this case. As Mr. Arsenault said, 10:57:38
13 and Mr. Zimmerman before him, we are dealing with a single 10:57:50
14 product, manufactured by a single company in a 10:57:56
15 co-ventureship arrangement with a second company. 10:58:03

16 Their conduct, and that was one of the messages 10:58:09
17 of that presentation by Mr. Arsenault, their conduct has 10:58:12
18 been uniform with regard to Baycol. Their advertising, 10:58:17
19 their marketing, their knowledge, their relationships with 10:58:25
20 the FDA, their relationships with their sales force, and 10:58:29
21 the doctors. And it has a short life, three and a half 10:58:35
22 years, 42 months. We are not talking about tobacco for 40 10:58:40
23 years. We are not talking about penile implants, multiple 10:58:47
24 products, multiple models, multiple modifications. We are 10:58:54
25 not talking about Bridgestone-Firestone, millions of tires 10:59:02

1 in 67 formats. We are talking about a contained 10:59:07

2 environment. 10:59:11

3 And we are talking about consequences that have 10:59:13

4 been referred to this mornings as signature. There is a 10:59:18

5 signature to the consequences of Baycol, the muscle aches 10:59:22

6 and pains, the Rhabdo, the renal failure, the instinct 10:59:27

7 renal failure. 10:59:36

8 It's not like many of these cases in which you 10:59:37

9 get allegations of injuries that are circumferal, that come 10:59:42

10 from left field, right field. This is a line. It's a 10:59:47

11 single, progressive series of events. 10:59:52

12 We think the context of this case is unique. We 10:59:58

13 think this context permits you to use the word in Rule 1 to 11:00:08

14 administer this case, to administer it. 11:00:15

15 Now, I appreciate that it has the feeling of a 11:00:25

16 wooly mammoth -- some ill-defined blob. 11:00:38

17 THE COURT: How about a black hole. 11:00:40

18 MR. MILLER: Black hole. 11:00:46

19 THE COURT: I get sucked into it and then we are 11:00:48

20 here again. 11:00:52

21 MR. MILLER: You have a feeling of the case, if 11:00:54

22 you look at the mortality table, it will outlive you? 11:00:57

23 THE COURT: Yes. 11:01:01

24 MR. MILLER: Yes. I suppose if you look at the 11:01:03

25 wholesale level, it's forbidden, it's forbidden. Even 11:01:06

1 though I say again and again, it's a case that's 11:01:10

2 dimensionalized. It isn't of the dimension of those other 11:01:18
3 cases. And we believe that there are lots of tools in the 11:01:20
4 proverbial toolbox. We believe that this is not simply a 11:01:26
5 binary choice, certify, don't certify. We believe that 11:01:34
6 there are alternatives. 11:01:43

7 Now, in the supplemental brief, the writers 11:01:46
8 started to develop a combination that has some favor with 11:01:55
9 some Judges, and that is the so-called 23(b)(3) 11:02:00
10 certification, and then using the 23(c)(4)(a) issue 11:02:06
11 mechanism. 11:02:16

12 We think this case satisfies 23(b)(3). We start 11:02:21
13 with that as our platform. You look at this case, and we 11:02:25
14 believe it has predominance. I think Mr. Arsenault 11:02:33
15 demonstrated the predominance, from soup to nuts. It's all 11:02:36
16 common conduct. It is all common conduct that applies to 11:02:42
17 each and every member of the class. In the words of the 11:02:46
18 Jenkins opinion in the Fifth Circuit, the resolution of 11:02:51
19 those common repetitive duplicative questions will 11:02:54
20 significantly advance the resolution of the action. And 11:03:02
21 that's sort of the test. It's not a nose counting test. 11:03:06
22 It's not it's bigger than a bread box or smaller than a 11:03:10
23 teacup. It's can I see that all of this singularity of 11:03:15
24 conduct is common and can be resolved on a common basis, 11:03:21
25 and that's what (c)(4)(a) is all about. 11:03:33

1 Now, there are pros to the class action. The 11:03:42

2 obvious first one is the resource question. It's what I 11:03:49
3 read to you from the note to Rule 1, the duty to administer 11:03:59
4 so it's fair, so it's expeditious and economically, which, 11:04:06
5 of course, is a reformulation of what's in the rule itself. 11:04:16
6 The ability to resolve on a class-wide basis all 11:04:19
7 of the factual questions relating the Defendants' conduct 11:04:24
8 holds promise for enormous economies and efficiencies. Few 11:04:31
9 resources, both in the form of energy for the Bench, for 11:04:41
10 the lawyers, for the parties and the cost. What sense -- 11:04:47
11 everybody recognizes that when you have a common question 11:04:50
12 that stretches across a large class, the repetitive inquiry 11:04:54
13 into what did the Defendants know when. Did they withhold 11:05:00
14 information about adverse results? Did they conceal things 11:05:10
15 from the FDA? Did they deep six any talk about the 11:05:14
16 withdrawal from the U.K. Again and again and again, no, 11:05:25
17 that's what (c)(4)(a) is for. 11:05:34
18 So, you get enormous savings of resources, and 11:05:38
19 you get a bonding effect on class members, either through 11:05:42
20 direct estoppel, if it's part of the case tried, or 11:05:51
21 anywhere else in the federal system under the Park Lane 11:05:56
22 Hosiery case. And you can't swear today that you'll get it 11:06:01
23 in each and every state court because you can't tell the 11:06:04
24 Texas court what res judicata is all about, but Park Lane 11:06:08
25 is not a federal phenomenon. New York has it, and most 11:06:13

1 states now accept offensive, non-mutual collateral 11:06:20

2 estoppel. At the very least, a well-tryed determination of 11:06:21
3 all common issues will be very persuasive in any court. 11:06:28
4 Now, we come to fairly. We know -- we know that 11:06:37
5 if something is not pulled out of the toolbox that would 11:06:43
6 allow some form of aggregation, there will be thousands and 11:06:48
7 thousands of people who will never be compensated, assuming 11:06:53
8 they were entitled to be compensated. They will never get 11:07:00
9 notice. They have small claims that are either of negative 11:07:04
10 value or modest value, not attractive to lawyers. They may 11:07:08
11 live in parts of the country in which they have no access 11:07:14
12 to legal services, or they may be part of American's 11:07:18
13 disenfranchised. A class forum will at least move the ball 11:07:23
14 for them. 11:07:28

15 Curiously, something that you don't see discussed 11:07:34
16 much is let's think of something unthinkable to Plaintiffs' 11:07:38
17 lawyers that they win some of these issues. That they win 11:07:43
18 on, say, muscle aches. Is that the case? Think of the 11:07:48
19 resources that you save by shrinking the case, because now 11:07:56
20 you have no individual litigation on an issue that's out of 11:08:02
21 the case. That's almost unquantifiable, but there are 11:08:07
22 aspects here that could produce that result. 11:08:13

23 Maybe it's determined that the FDA warning, this 11:08:21
24 FDA warning, that FDA warning was adequate. Failure to 11:08:24
25 warn may disappear. 11:08:31

1 Maybe on the common issue trial, the conduct 11:08:36

2 doesn't look as severe as Mr. Arsenault presented today. 11:08:40
3 Maybe punitive damages falls out. So, it's a very funny 11:08:47
4 business that the common issue determinations can work both 11:08:54
5 ways. But the net effect either way is to save resources, 11:08:58
6 to give people a day in court, maybe not a literal day in 11:09:04
7 court, but at least a figurative day in court. They have 11:09:13
8 all sorts of due process protections through the class 11:09:15
9 forum. They get notice. They get adequacy of 11:09:19
10 representation. On the damage side, they have the ability 11:09:23
11 to opt out. 11:09:26
12 Now, we come to the part you don't like. They 11:09:29
13 have you. You're are. You're scrutinizing. You're 11:09:34
14 keeping the lawyers in place, and we know lawyers are like 11:09:38
15 herding cats. You are going to determine the fairness, the 11:09:44
16 adequacy and the reasonableness of any settlement. You are 11:09:50
17 going to determine the propriety of an attorney's fee, 11:09:54
18 which on a class-wide basis may mean a good reward for 11:09:58
19 them, but when distributed all over the class means more 11:10:08
20 money in the class member's pocket. All of is these 11:10:13
21 protections are available through the class forum, even if 11:10:17
22 it's just a (c)(4)(a) common issue adjudication. 11:10:22
23 You ask how would it look. It would look -- Mr. 11:10:28
24 Arsenault has just presented the Plaintiffs' case. That's 11:10:31
25 what it would look like. And you would have, and must 11:10:34

1 confess, you would have to write -- but they have 11:10:40

2 counsel -- a Rule 49 verdict form. And it would take 11:10:47
3 several pages. And everybody would worry as to whether it 11:10:54
4 was comprehensible to the jury. 11:11:00

5 Now, we here we hit a philosophical wall. Do you 11:11:00
6 believe in the jury system or don't believe in the jury 11:11:08
7 system? Down you can construct a verdict form that they 11:11:13
8 can comprehend and give you answers and take out all these 11:11:17
9 common issues. Being an old fogey, I believe in the jury 11:11:21
10 system. We do things like this right now. We know it's 11:11:26
11 done in conspiracy cases, civil RICO cases. It was done in 11:11:31
12 Exxon Valdez. The verdict form, I'm told, was over 20 11:11:39
13 pages in length. There are enormous resources out there, 11:11:42
14 done by people who have fought about this. There are 11:11:50
15 models of verdict forms. There is a book by Mr. Eaves. We 11:11:53
16 have things in the toolbox. We can use Rule 49 in a 11:12:01
17 sophisticated fashion. But there is a work level attached 11:12:07
18 to it. 11:12:14

19 It's easy for me to talk about your spending 11:12:18
20 time, Your Honor. You are 1407 Judge. There was a 11:12:20
21 decision made that there are commonalities here. Rule 1 11:12:30
22 does say and administer. You're the general. A lot of it 11:12:35
23 can be delegated, but there is no doubt there is a work 11:12:41
24 portion attached to it. But you can get these common 11:12:48
25 issues, which are at the spine of this case, resolved in a 11:12:51

1 highly refined trial. And when I say these common issues, 11:12:59
2 I'm taking it all the way over to punitive damages. Mr. 11:13:12

3 Arsenault's presentation, much of that conduct is the 11:13:12
4 conduct that would be presented on punitive damages 11:13:12
5 presentation, up or down, that's it. 11:13:17

6 So, you come through all of these common issues 11:13:23
7 right over to punitive damages, unified result, available 11:13:27
8 to everyone, and it enables a judge who has invested in 11:13:31
9 this black hole or millstone or adventure to control, to 11:13:47
10 control it, to make sure it goes from the woolly mammoth to 11:13:57
11 a sleek horse, rather than going from a woolly mammoth to a 11:14:05
12 woolly mammoth with a gland condition. 11:14:16

13 There is another element to this, call me an 11:14:20
14 academic. A reality of one-on-one litigation is that it 11:14:23
15 has virtually no transparency. A class action centralized 11:14:28
16 in a federal court before a managing judge has 11:14:36
17 transparency. All relevant voices can speak because they 11:14:41
18 know what's going on. 11:14:45

19 Now, it is true, and this is philosophical again, 11:14:47
20 I said before that one of the consequences of dispersion is 11:14:53
21 that hundreds, if not thousands of people, who believe they 11:14:58
22 have been injured by Baycol will never be heard from. Some 11:15:04
23 people might say that's good, that's good. Why motivate 11:15:13
24 cases. That's philosophical. In the world of some judges 11:15:20
25 on the Seventh Circuit, that's the market. In the world of 11:15:28

1 other people, it's not fair. It's a fortuity that's just 11:15:33
2 plain not fair. That's so philosophical, so subjective, 11:15:42

3 only you can think that one through. 11:15:51

4 Now, let me give you a variation or offer you a 11:15:54

5 variation. According to a census of cases that you'll find 11:15:57

6 in Volume 3, Tab E of your Bench books, Plaintiffs' side, 11:16:04

7 there is a census of cases, and something is very striking 11:16:11

8 about it. According to this census, which spoke as of 11:16:18

9 January 31st, there were 805 cases on your docket, exceeded 11:16:24

10 only by Pennsylvania where there are 3,031 cases. The 805 11:16:33

11 cases are the Minnesota cases. The 3,031 cases are the 11:16:44

12 Pennsylvania cases. 11:16:51

13 We believe there are alternatives, Your Honor. 11:16:55

14 It's almost a smorgasbord. I've only thus far described 11:16:58

15 one, the (b)(3)(c)(4)(A), the combination. Get the common 11:17:08

16 things adjudicated, the rest go home or settled. We live 11:17:14

17 in a world in which 97, 97-plus percent of all federal 11:17:19

18 civil actions never reach trial. It's a reality. 11:17:26

19 Suppose you certify the Minnesota class, had full 11:17:31

20 adjudication, and then dealt with the individual issue of 11:17:41

21 an individual causation of damage at the back end if you 11:17:45

22 got the back end. That certainly would give you a very 11:17:50

23 good indication as to whether you could do the whole thing. 11:17:54

24 That's a contained group. You've got jurisdiction over 11:18:00

25 them, probably no choice of law problem. To me it's 11:18:04

1 somewhat analogous to what Judge Spiegel, who is going to 11:18:09

2 do or did do in Teletronics, summary judgment trial. 11:18:17

3 Let's do a dry run and see if anything works. 11:18:25

4 Now, you can take that Minnesota class all the 11:18:29

5 way through. Learn from it. I think one lesson that 11:18:31

6 powerfully comes through from Judge Bectal's opinion in 11:18:39

7 diet drugs is you don't have to do everything in one day. 11:18:47

8 Rome wasn't built in a day, and Baycol can't be solved in a 11:18:53

9 day. He took a baby step, a tentative certification of a 11:19:00

10 medical monitoring class. Judge Spiegel in effect did the 11:19:05

11 same thing by saying I'm going to have a summary jury 11:19:10

12 trial. A piece of the action, a significant piece. We're 11:19:13

13 talking 17 point something percent of all the Baycol cases 11:19:17

14 in the federal court, 17-plus percent are there in 11:19:22

15 Minnesota. You can have a Pennsylvania class, too. 11:19:27

16 Pennsylvania class decided under Pennsylvania law, common 11:19:31

17 issues. You probably have to send those back to 11:19:36

18 Pennsylvania, but that's not a baby step, that's a giant 11:19:39

19 step. I think the Minnesota resolution is a giant step, 11:19:43

20 too. Those are all the possibilities -- other 11:19:48

21 possibilities. 11:19:54

22 Here's another possibility. For reasons I don't 11:19:55

23 know, Federal Rules 16(c)13 and 42(b) talk about 11:19:59

24 consolidation for resolution of individual issues. You 11:20:10

25 could do that for the Minnesota cases. You could have a 11:20:16

1 unitized trial on the common issues under 42(b), encouraged 11:20:21

2 by one of those amendments to Federal Rule 16 I described a 11:20:28

3 few minutes ago. Federal Rule 16 says one of the things in 11:20:34
4 the pretrial management toolbox is consolidation of a 11:20:38
5 single issue of adjudication. 11:20:44

6 Now, you might ask what's the difference between 11:20:48
7 that and a class action. Well, I could be puckish about it 11:20:49
8 and say you wouldn't be vulnerable to a 23(f) appeal, 11:20:55
9 assuming that you didn't want to embrace the 23(f) appeal 11:21:01
10 to get the beast off your back for a year. But that's 11:21:05
11 inconsistent with the exigency of time. This is an old 11:21:11
12 class. These people are not young. You don't go on statin 11:21:18
13 until fairly late in life, by and large. 11:21:22

14 In any event there wouldn't be a 23(f) appeal. 11:21:26
15 There wouldn't be any of the hassling about the class 11:21:30
16 action, class action notice, class action certification, 11:21:34
17 class action settlement, class action this, class action 11:21:38
18 that. 42(b) consolidated trial on common issues. If need 11:21:42
19 be, you then go to Phase 2 and adjudicate the individual 11:21:50
20 issues if you're dealing with Minnesota group. You get the 11:21:55
21 same power of formal adjudication you would have under 23. 11:21:59
22 You could make sure that those due process procedures 11:22:04
23 safeguards that are attendant to the class action were 11:22:07
24 provided in 42(b). You can insist on adequacy of counsel. 11:22:12
25 You can insist on anything you want, the notice. So, 11:22:20

53

1 that's another possibility. 11:22:22

2 You could do that for the monster class, too. 11:22:26

3 Instead of certifying under (b)(3), (c)(4), just take the 11:22:30
4 common issues under 16(c)(13) and 42(b), the entire class. 11:22:36
5 And, again, get out of the religiosity of the class action. 11:22:43
6 All I'm going is illustrating that there are things in the 11:22:52
7 toolbox. 11:22:55

8 Let me throw out something else. And I guess 11:22:58
9 because I am of an older generation, and I am worried about 11:23:04
10 an elderly class, and do think public health is a value in 11:23:09
11 our society, maybe the first step, a baby step or not so 11:23:17
12 baby a step would be if memory serves, Your Honor, June 6, 11:23:24
13 2003, the anniversary of D-Day, you set something up for 11:23:31
14 trial. One of the things you can front load on that day is 11:23:43
15 medical monitoring. As Mr. Arsenault made clear, just 11:23:49
16 about everything on medical monitoring is a common 11:23:59
17 question. It's a common question. 11:24:05

18 Medical monitoring is time sensitive. If you're 11:24:15
19 going to get some public health benefits, some 11:24:20
20 prophylactics, you are going to develop epidemiological 11:24:24
21 data to try to move forward with dealing with rhabdo and 11:24:29
22 renal diseases, sooner is better than later, and it moves 11:24:34
23 forward, it moves forward. 11:24:40

24 By the way, if you don't use something in the 11:24:44
25 tool box, there will never be any medical monitoring by 11:24:47

1 anybody. Any individual litigation can't produce it. And 11:24:51
2 even dispersed aggravated litigation won't do it. Medical 11:24:59

3 monitoring in and of itself requires aggregation, otherwise 11:25:07
4 it's useless, otherwise it won't achieve it's objective 11:25:17
5 ever trying to bring some health knowledge to people. 11:25:19
6 It's estimated that maybe 280,000 people in the 11:25:22
7 larger class have never been tested. And on June 6, maybe 11:25:28
8 you will want to adjudicate this question of medical 11:25:35
9 monitoring. Is it needed? Are there tests? Will it do 11:25:40
10 any good. 11:25:46
11 It's a bench trial. It's all equity. It may not 11:25:49
12 look like a thou shalt not injunctive order, but it's 11:25:54
13 equity, it's equity. It's a bench trial. 11:25:59
14 So, again, there are lots of ways to do it, and 11:26:14
15 I'm not standing here saying you should do A or B or C or D 11:26:17
16 or A and B or E and D, because these things can be 11:26:24
17 combined. They can be staged in sequence. 11:26:31
18 Judge Bechtal in diet drugs started with a 11:26:35
19 tentative medical monitoring class. I think he felt that 11:26:41
20 the public health elements for the diet drug population 11:26:47
21 should get primacy. Everything else was reserved, but it 11:26:54
22 seems to be critical that you maintain control of the wooly 11:27:01
23 mammoth. Failure to certify anything or take a baby step 11:27:05
24 or a giant step will diffuse, will disaggregate, will 11:27:17
25 disassemble, which I think you've worked very, very, very 11:27:24

1 hard to hold together. 11:27:31
2 There was a perfect illustration of that a couple 11:27:33

3 of days ago on remand on Bridgestone-Firestone back to 11:27:36
4 Judge Barker back in Illinois. Irony of ironies. The 11:27:38
5 defense lawyers wanted her to enjoin the lawyers and 11:27:46
6 parties from fleeing and bringing state-based or state-wide 11:27:51
7 class actions. And an opinion that has a lot of doesn't 11:28:00
8 say, but you can feel, she said, hey, defense, you told me 11:28:13
9 I couldn't aggregate. Seventh Circuit has agreed with you. 11:28:20
10 I no longer have the ability to control those people. I 11:28:26
11 can't always act them. They're gone. They're gone. You 11:28:31
12 won't have it both ways. You can't tell me I can't 11:28:37
13 aggregate for class purposes, but I can aggregate to order 11:28:44
14 all of those people to do X or Y or not Z. 11:28:49
15 I think it's a very interesting object lesson. 11:28:54
16 It demonstrates the importance of the maintenance of 11:28:58
17 control by the 1407 Judge, and that's achieved I think, by 11:29:02
18 doing something, whether it's medical monitoring, whether 11:29:11
19 it's a common issue trial, whether it's both. 11:29:15
20 To be sure, so much of this is about philosophy. 11:29:27
21 It's about attitudes, beliefs. Just as I can't teach 11:29:33
22 Ethics at the law school, I say nothing on that subject. 11:29:41
23 We believe you should do something. We believe 11:29:49
24 that in the course of this presentation, you will hear from 11:29:50
25 Mr. Beck. You've got bench books, something that you feel 11:29:57

1 is right for this case. There is not a question of right 11:30:03
2 or wrong in the abstract. This is a question of your 11:30:08

3 discretion to decide what is right for this case. This, I 11:30:12
4 think, singular case involving a highly specific and, thus 11:30:17
5 far, relatively unique fact pattern. 11:30:22
6 Let me close, since I am in this building, by 11:30:35
7 reading some words written 13 years ago by someone who is 11:30:38
8 now your chief judge. This is from In re Worker's 11:30:43
9 Compensation, factually, not at all relevant. Judge 11:30:52
10 Rosenbaum says, Defendant's parade of horror is chimerical. 11:30:57
11 They know, as does this Court, that this case can be 11:31:04
12 managed. It does not take a battalion of rocket scientists 11:31:09
13 to handle a large case. If the Plaintiffs' claims are 11:31:14
14 substantiated, the class action mechanism is clearly the 11:31:20
15 most efficient means of resolving the many claims which may 11:31:25
16 be asserted. If the case were not handled as a class, 11:31:30
17 thousands of small claims would be either brought or 11:31:34
18 unjustly abandoned. The first possibility would be a flood 11:31:41
19 of cases. The second would involve individual claims 11:31:44
20 abandoned because of costs. Things change, but some things 11:31:51
21 remain the same. But Judge Rosenbaum saw as that duality 11:32:00
22 in 1990 is just as true in 2003. Thank you. 11:32:06

23 THE COURT: Thank you. 11:32:16

24 MR. ZIMMERMAN: Your Honor, I expect maybe your 11:32:35
25 reporter would like a break. She asked me how long it 11:32:37

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1 would be and I said an hour. 11:32:43

2 THE COURT: Let's take a 15-minute break, 15 11:32:44
3 minutes. 11:32:48

4 (Recess taken.)

5 MR. ZIMMERMAN: Can I ask the Court if you're 11:32:50
6 going to take a lunch break? 11:32:55

7 THE COURT: Yes, we'll take a lunch break, 12:30 11:32:58
8 to 1:30. 11:33:00

9 THE COURT: Mr. Zimmerman,. 11:49:57

10 MR. ZIMMERMAN: I thank you, Your Honor. At this 11:50:06
11 time, I'd like to introduce Elizabeth Cabraser from San 11:50:06
12 Francisco and New York who is going to talk about the 11:50:11
13 refund class and also make some comments on issues and 11:50:13
14 follow up to Professor Miller's presentation. 11:50:18

15 THE COURT: Okay. 11:50:22

16 MS. CABRASER: Good morning, Your Honor. 11:50:39

17 THE COURT: Good morning. That whole podium can 11:50:42
18 be lowered. On the side is a button. 11:50:46

19 MS. CABRASER: How did Your Honor know I needed 11:50:51
20 to do that. That's a wonderful thing. I don't have to 11:50:53
21 stand on a box. That's what keeps me from being a 11:51:03
22 distinguished trial lawyer. If you have to stand on a box, 11:51:09
23 it's very, very difficult to maneuver persuasively with a 11:51:15
24 jury, anyway, and it adds to the length of trials. 11:51:17
25 Before I start, Your Honor -- 11:51:21

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1 THE COURT: What trial lawyer doesn't stand on a 11:51:22
2 box? (Laughter). 11:51:25

3 MS. CABRASER: Well, I need to stand on a real 11:51:27

4 one. Before I start just some housekeeping matters in 11:51:30
5 terms of some of the document that we are speaking from 11:51:40
6 this morning. They are in a bench book, Your Honor. Most 11:51:44
7 of the actual presentation materials are in Volume III of 11:51:50
8 your bench book, including the printout form of the slides 11:51:52
9 that were shown during Mr. Arsenault's presentation and the 11:51:57
10 actual documents to back those up. Those are -- the slides 11:52:01
11 are at Tab A. The supporting documents bates number order 11:52:05
12 are at Tab B. Some outlines of Professor Miller's remarks 11:52:11
13 are at Tabs C and D. The case census that Mr. Miller 11:52:18
14 referred to which we believe was prepared by Defendants and 11:52:24
15 appears to be pretty accurate in terms of the number of 11:52:28
16 federal cases that are before you as part of the MDL is at 11:52:30
17 Tab E. And that's where the data on the 805 Minnesota 11:52:35
18 filings and the 3,031 federal cases transferred in from 11:52:42
19 Pennsylvania is taken. 11:52:48
20 The Bridgestone-Firestone order from Tuesday of 11:52:50
21 Judge Barker denying the Defendants' joint motion to enjoin 11:52:56
22 all state court class proceedings nationwide is included as 11:53:01
23 Tab H. We don't have a signed copy because that comes out 11:53:07
24 on the website and was faxed around by Judge Barker. I do 11:53:12
25 understand that that is currently under petition for appeal 11:53:18

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1 to the Seventh Circuit. 11:53:23

2 What you don't have in the bench book is kind of 11:53:26

3 the census on that litigation. Just for comparison 11:53:34

4 purposes in the wake of the Seventh Circuit's reversal of 11:53:35
5 the class certification order, a number of cases were 11:53:38
6 commenced in state courts across the country. One of those 11:53:42
7 has been certified as a statewide class in Illinois, I 11:53:47
8 believe. Another one is up for the class certification 11:53:50
9 hearing. Various state court systems have gotten involved 11:53:51
10 and pursued their own coordinated proceedings in an attempt 11:53:55
11 to manage the many Bridgestone-Firestone proceedings that 11:54:00
12 were commenced of necessity to protect the Plaintiffs' 11:54:06
13 claims in the wake of that order. 11:54:09

14 And if the Bridgestone-Firestone cases before 11:54:12
15 Judge Barker were a black hole and a case that presented 11:54:16
16 management challenges, I think right now that litigation, 11:54:20
17 despite the best efforts of the Plaintiffs' counsel across 11:54:23
18 the country to continue to coordinate it and to keep all 11:54:27
19 the courts apprised of what's going on so that the courts 11:54:30
20 at least have information is now a management challenge of 11:54:40
21 many orders of magnitude greater. We have a system of 11:54:42
22 black holes in that universe many courts will have to deal 11:54:47
23 with on the same issues and claims. 11:54:50

24 So, I was going to speak to you this morning, 11:54:53
25 Your Honor, about the refund class, and I will do that. 11:54:56

1 But in light of your question, I think I will start first 11:54:59
2 with what seems to be most pertinent and relevant. Indeed, 11:55:05
3 I think it's crucial to the questions and the decisions and 11:55:12

4 the choices that have been presented to you in the form of 11:55:14
5 the Plaintiffs' motion for class certification in these MDL 11:55:20
6 proceedings. 11:55:25

7 And I think the one thing that most troubles 11:55:27
8 Judges who are confronted with cases thing cry out for some 11:55:29
9 form of aggregation is the absence of the ideal class 11:55:34
10 action trial plan, graven in stone and descending from the 11:55:43
11 heavens or wherever the federal rules come from to provide 11:55:50
12 clear, precise, unambivalent, unequivocal guidance that is 11:55:54
13 not only easy and quick, but appeal proof and 11:56:02
14 non-controversial, and we have not achieved that level of 11:56:08
15 certainty in the field of complex litigation and 11:56:17
16 aggregation and complex trials. 11:56:19

17 And if you asked me if I believed in class action 11:56:24
18 trials, I would have to revert to that old song about do 11:56:29
19 you believe in infant baptism. Yes, I've seen it done. 11:56:37
20 Well, yes, I have seen class action trials done. I've seen 11:56:43
21 plaintiffs win them, I've seen plaintiffs lose them. I've 11:56:48
22 been involved in the planning and the structuring and the 11:56:51
23 conduct of some of them. And there are other lawyers in 11:56:54
24 this court with even greater experience than mine who have 11:56:57
25 participated in the actual conduct of mass tort class 11:57:03

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1 action trials. 11:57:06

2 So, we do have a small universe of guide points 11:57:08
3 to look to see which of those techniques and which of those 11:57:15

4 structures might be appropriate in this case. In our 11:57:20
5 briefing, we attempted to describe some of those. Some of 11:57:25
6 the class certification decisions in other mass tort cases 11:57:31
7 such as the class certification decision in Copley 11:57:36
8 Albuterol, and the final class certification decision of 11:57:42
9 Judge Spiegel in Teletronics after the case was first 11:57:48
10 certified and then decertified and then recertified do 11:57:54
11 include or append trial plans. Those are trial plans very 11:57:57
12 specifically designed for those cases. 11:58:00

13 And if you look at those trial plans in Copley 11:58:03
14 Albuterol, which was a single prescription medication case 11:58:07
15 MDL from all across the country involving multiple states 11:58:15
16 laws, and if you look at Teletronics, a medical device 11:58:19
17 case MDL from all across the country involving multiple 11:58:23
18 state laws, what you see is very much like what Professor 11:58:30
19 Miller described to you just a moment ago. You see classes 11:58:33
20 certified under Rule 23(b)(3). You see the courts 11:58:38
21 selecting common issues for a Phase I trial, utilizing Rule 11:58:43
22 23(c)(4)(a) expressly or not, depending upon the style of 11:58:47
23 the opinion. You see medical monitoring claims treated as 11:58:51
24 a common issue and certified, either under 23(b)(2) or 11:58:54
25 23(b)(2) and (b)(3), because I think it's fair to say that 11:59:00

1 most courts preclude that while predominance and 11:59:06
2 superiority are not requirements for certification of
3 medical monitoring claims, those requirements are usually 11:59:13

4 met simply because the medical monitoring claim shares 11:59:14
5 common liability issues and common fact patterns with the 11:59:17
6 other claims in the case. 11:59:21

7 What you typically see would be Judges as MDL 11:59:24
8 Judges, even before Lexecon who recognized that whether or 11:59:29
9 not the Plaintiffs had a right to take their individual 11:59:34
10 cases back to transferor or district or other courts for 11:59:37
11 trial, they might wish to and, indeed, their personal 11:59:43
12 injury and wrongful death claims were sufficiently serious 11:59:47
13 and had sufficient value to vest the Plaintiffs with a real 11:59:53
14 interest in controlling insofar as they could without 11:59:58
15 clashing with other provisions of the federal rules. Some 11:59:58
16 individual destiny in their cases. So, you see courts 12:00:03
17 balancing those interests. 12:00:07

18 So, it's not to say that a mass tort personal 12:00:09
19 injury wrongful death trial arising from a dispersed mass 12:00:14
20 tort like a medical device or a drug could not be tried 12:00:18
21 front to back, all phases, including damages, in one court, 12:00:22
22 courts typically do not go there. They determine, I think 12:00:27
23 quite pragmatically, that the resolution of the common 12:00:33
24 issues that relate to the Defendants knowledge, conduct, 12:00:38
25 duty, the characteristics of the product itself, whether or 12:00:41

1 not it's detective, whether or it's dangerous, whether or 12:00:44
2 not it can cause a specific disease. The resolution of 12:00:49
3 those issues by one jury will significantly advance either 12:00:51

4 the resolution or the adjudication of the remaining issues 12:00:55

5 in the case. 12:00:57

6 Because Albuterol and Telectronics were certified 12:00:57

7 and tried before the United States Supreme Court issued its 12:01:01

8 recent decision in Cooper Industries v. Letterman Tool 12:01:08

9 Group, you see courts reluctant to place or phase the 12:01:13

10 punitive damages issue in the phase one common issues 12:01:21

11 trial. And the courts have reserved that in the past in 12:01:26

12 some fashion for individual adjudication. 12:01:28

13 Other courts have included punitive conduct and 12:01:33

14 punitive damages as a phase or multi-phase jury trial, in 12:01:36

15 the Marcos Human Rights litigation, for example, and Exxon 12:01:43

16 Valdez case, which I will get to in a moment. But Judge 12:01:50

17 Spiegel in Telectronics and Judge Brimmer in Albuterol were 12:01:56

18 not faced with a Supreme Court that has now prescribed the 12:02:04

19 factual determinations and the policy considerations which 12:02:09

20 must be made by any jury in any federal or state trial 12:02:12

21 involving punitive damages. 12:02:19

22 The BMW decision, and more expressly, the Cooper 12:02:19

23 decision have, in effect, created a federal common law on 12:02:26

24 punitive damages law, yet, the state judge is still free to 12:02:29

25 decide whether he will allow punitive damages on a given 12:02:35

1 claim. But any jury anywhere must now consider certain 12:02:37

2 factors and answer certain questions in deciding that. And 12:02:41

3 as the Supreme Court said in Cooper, the Seventh Amendment 12:02:47

4 is not implicated in those determinations. They are not 12:02:51
5 pure fact determinations. They are mixed. There is a 12:02:57
6 legal element, an equity element in those determinations, 12:02:59
7 so much so that it's not only all right, but now mandatory 12:03:04
8 that when the jury issues a punitive damages verdict, it is 12:03:08
9 subject to de novo review. 12:03:14

10 We have a situation now where the Supreme Court 12:03:15
11 has said that punitive damages is of constitutional 12:03:19
12 dimension, and the defendant has a due process right to be 12:03:25
13 exposed to a just level of punitive damages and to be 12:03:29
14 protected against excessive punitive damages on a single 12:03:31
15 course of conduct or a single product or a single event. 12:03:37
16 And that goal, that mandatory goal that is now imposed on 12:03:41
17 the federal and state court systems by the Supreme Court is 12:03:46
18 difficult, if not impossible, we suggest, to achieve 12:03:50
19 through multiple proceedings in multiple courts on punitive 12:03:53
20 damages involving the same conduct and the same product, 12:03:58
21 each going up to multiple appellate courts for mandatory de 12:04:01
22 novo review. 12:04:08

23 We see no way to get to the Supreme Court's goal 12:04:09
24 in a situation involving multiple plaintiffs and a mass 12:04:13
25 tort through those dispersed proceedings. That situation 12:04:16

1 was not faced by earlier MDL courts looking at mass tort 12:04:19
2 cases and how to phase trials and how to gather common 12:04:24
3 issues together and how to reserve individual issues. 12:04:32

4 So, the trial plan we would ask you to consider 12:04:34
5 in this case does differ from the trial plans that were 12:04:39
6 described in Copley and in Telectronics and which were 12:04:42
7 quite successful in persuading the parties that the cases 12:04:45
8 could be managed as class actions in providing the parties 12:04:50
9 sufficient information to settle them on an in-forward 12:04:54
10 basis and resolving thousands of claims in a fair, speedy 12:04:56
11 and inexpensive way. 12:05:00

12 These days, it seems, though the Supreme Court 12:05:03
13 has not spoken directly to this issue, that any judge faced 12:05:06
14 with the management of a mass tort case and personal injury 12:05:10
15 wrongful death and consumer claims that give rise to the 12:05:17
16 possibility of exposure to punitive damages should 12:05:21
17 seriously consider to the extent to which one jury 12:05:24
18 addressing as part of its common issues verdict form the 12:05:32
19 questions that the Supreme Court has said any jury must 12:05:35
20 answer on a defendant's punitive conduct, on its 12:05:41
21 reprehensibility, on the appropriate level of punishment 12:05:44
22 for that conduct. 12:05:48

23 This could be done in a number of ways. Years 12:05:49
24 ago, it seems like 15 years ago or 16 years ago, I guess it 12:05:54
25 was, in the Jenkins case, which were a group of asbestos 12:06:02

1 cases consolidated before a district judge in Texas, the 12:06:06
2 court decided to craft a trial plan which determined 12:06:09
3 punitive conduct in Phase I and asked the Phase I jury to 12:06:14

4 answer a series of questions about the defendant's conduct 12:06:18
5 with asbestos. Did they know it was dangerous. The state 12:06:21
6 of the art defense that they had. And the jury was asked 12:06:27
7 to assess a multiplier of punitive damages which could then 12:06:30
8 be applied to perspective compensatory verdicts in 12:06:35
9 different phases of the case or in other phases or other 12:06:39
10 cases. The Fifth Circuit upheld that plan as 12:06:40
11 constitutional. It was never overruled despite all the 12:06:44
12 vagaries of asbestos litigation in Texas. 12:06:50

13 That is one model the Court could follow today. 12:06:56
14 In other words, Your Honor, you can certify the classes on 12:06:57
15 injury and refund through 23(b)(3). You could delineate 12:07:00
16 the common issues for the common issues trial. Those 12:07:06
17 common issues could include questions regarding the 12:07:11
18 Defendants' punitive conduct, and the jury could be asked 12:07:15
19 to establish a ratio he or multiplier that would be imposed 12:07:17
20 to reflect a fair and just proportion of punitive damages 12:07:22
21 on prospective compensatory awards, compensatory awards 12:07:26
22 rendered by that jury in favor of the named representative 12:07:30
23 Plaintiffs in your common issues trial which could be front 12:07:34
24 to back as to them and the ratio that could be applied in 12:07:38
25 later cases. 12:07:42

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1 Your Honor need not go that far. The jury can 12:07:42
2 answer the questions about punitive conduct without a 12:07:46
3 multiplier, and the Your Honor can go farther and ask that 12:07:48

4 jury in the common issues trial to go ahead and calculate 12:07:51
5 the aggregate amount of punitive damages, if any, that 12:07:56
6 would be imposed against each of the Defendants for its 12:08:00
7 conduct and its role in the research, development, 12:08:04
8 marketing, promotion and sale of Baycol. 12:08:08

9 Information would have to be provided to the jury 12:08:13
10 about the harm caused by that conduct and the potential 12:08:16
11 harm because that is one of the Cooper factors, but that 12:08:21
12 could be done. It could be done through expert testimony. 12:08:24
13 It could be done through surveys of the members of the 12:08:28
14 class. 12:08:31

15 We realize as a tactical matter Plaintiffs' 12:08:31
16 lawyers like to maintain control over the punitive damages 12:08:37
17 component of their clients' claims because that adds value 12:08:41
18 to the claims and that could drive settlement. And that is 12:08:50
19 a legitimate, tactical consideration and we honor it. 12:08:50

20 We also recognize that this Court has a different 12:08:54
21 perspective, and institutional perspective and a 12:08:58
22 perspective of taking care to see that everyone is treated 12:08:59
23 fairly and the dynamics that drive settlements are 12:09:02
24 available to everyone. And although Defendants would not 12:09:06
25 ask for it, and, indeed, would say they don't need it 12:09:09

1 because they have done nothing wrong, this Court does have 12:09:13
2 an interest in seeing, as the Supreme Court has says it 12:09:18
3 must, that if the Defendants are exposed to punitive 12:09:22

4 damages, it is not excessive. It is not repetitive, and I 12:09:25
5 would suggest given the complexities of multiple de novo 12:09:30
6 review and the time delays, this Court has the 12:09:36
7 responsibility under Federal Rule 1 to see that money that 12:09:36
8 would otherwise be available to pay a fully adjudicated and 12:09:38
9 fair punitive damages award is not otherwise dissipated in 12:09:42
10 the transaction costs of endless, repetitive trials and the 12:09:46
11 inevitable de novo appeals. 12:09:51

12 This gets me to the experience aspect of this. 12:09:56
13 We are all victims of our experience. One of the class 12:10:00
14 action trials that I have seen done, and indeed was 12:10:04
15 implicated somewhat in the doing of it, was the Exxon 12:10:09
16 Valdez trial. Exxon Valdez was a mass accident case, and 12:10:14
17 the class claims were largely economic. But as District 12:10:20
18 Judge Hollins most recent decision in Exxon Valdez makes 12:10:28
19 very clear, and you have that, Your Honor, attached to the 12:10:33
20 Lockridge Declaration in your opinion briefing book, the 12:10:37
21 course of conduct that culminated in that accident was many 12:10:40
22 years in the making, and it was complex, and it was 12:10:45
23 contention. And the aftermath of that tanker's grounding 12:10:48
24 was complex and contentious in terms of its impact upon the 12:10:52
25 economies of the fishing industries in Alaska, the native 12:10:57

1 Alaskan societies and figuring out the factual complexities 12:11:04
2 of who was owed damages in what amount and for what was a 12:11:11
3 daunting task for the jury. I would submit a far greater 12:11:18

4 complexity than any set of questions, a common questions 12:11:23
5 jury would be asked to decide in this case. 12:11:27
6 We haven't given Your Honor a verdict form per 12:11:31
7 se. The rules and jurisprudence do not suggest that we 12:11:37
8 must, but we have given thought to lists of common 12:11:43
9 questions that are fact questions that a common issues jury 12:11:48
10 would -- could be asked to answer as factfinder in a common 12:11:53
11 questions trial or Phase I trial in this case. Some of 12:12:00
12 those are gathered in Volume III of your Bench book, and if 12:12:05
13 I could have Slide 50. We can show you some of them on the 12:12:10
14 screen. And these are not -- you can just keep going and 12:12:16
15 scroll through those. These are not the ultimate language 12:12:28
16 that might be used by the time the trial lawyers might be 12:12:28
17 through wrangling over jury instructions should look like 12:12:33
18 and how they should read, but they are many of the common 12:12:34
19 questions that any jury in any case would be required to 12:12:40
20 deal with on its way to a verdict on liability and damages. 12:12:44
21 And those common questions -- you can just go 12:12:51
22 through those a little quicker -- those common questions 12:12:53
23 don't include the list of questions and factors that the 12:12:58
24 Supreme Court has said must be asked in a punitive damages 12:13:03
25 case, but we have the best source of all for those 12:13:09

1 questions. We have the Supreme Court itself in Cooper 12:13:15
2 Industries telling us at 532 U.S. Page 1440 that there is a 12:13:21
3 uniform set of factors that must be utilized and questions 12:13:27

4 that must be answered in determining punitive conduct and 12:13:31
5 damages questions in every case by every Court. Number 1, 12:13:36
6 the degree or reprehensibility of the Defendant's conduct; 12:13:41
7 Number 2, the disparity between the harm or potential harm 12:13:42
8 suffered by the Plaintiffs and the punitive damages award 12:13:48
9 that's being requested; and, 3, the difference between the 12:13:51
10 punitive damages awarded by that jury and the penalties or 12:13:54
11 punishments authorized or imposed in comparable cases. And 12:13:58
12 that's what makes multiple punitive damages decision now so 12:14:02
13 problematic because someone has to have an overall view of 12:14:09
14 what the total exposure might be. And that could be a 12:14:14
15 reviewing Court, but more to the point, it could be a class 12:14:16
16 action common questions jury. 12:14:22

17 It's what the jury did in the Exxon Valdez case. 12:14:23
18 Exxon Valdez was certified as a class action at the 12:14:28
19 Defendants' request. Exxon, now Exxon Mobil, asked for 12:14:35
20 that, after the Plaintiffs had asked the federal court to 12:14:39
21 certify the class under (b)(3), and the federal Court 12:14:46
22 denied the motion. Exxon found itself in a 12:14:50
23 Bridgestone-Firestone situation. It had gotten what it had 12:14:55
24 asked for, and now it was faced with thousands of irate 12:15:00
25 claimants in state and federal court in Alaska, not across 12:15:06

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1 the country, but at least in two court systems, who wanted 12:15:09
2 a shot at punitive damages and somehow were going to have 12:15:12
3 to get it. 12:15:16

4 And, so, Exxon thought better of its previous 12:15:18

5 opposition of class certification and its invocation of its 12:15:21
6 Seventh Amendment and all the other arguments that 12:15:24
7 Defendants make against class trials. And Exxon swallowed 12:15:27
8 hard and asked the district judge to certify the class for 12:15:31
9 trial, to have one trial on the common questions of the 12:15:34
10 Defendants' conduct and its culpability, Phase I. Phase 12:15:38
11 II, the compensatory damages, if any, that ought to be 12:15:47
12 awarded by the thousands of people in the very complex 12:15:47
13 class system, the Exxon court certified. And in Phase III, 12:15:53
14 if there was a compensatory verdict or a determination of 12:15:55
15 compensatory harm, the total and punitive damages, if any, 12:16:02
16 that ought to be awarded for the Exxon Valdez incident, the 12:16:02
17 conduct that led up to it and it's after math. 12:16:09
18 In 1994, Judge Holland convened a jury and 12:16:13
19 conducted that trial in three phases and it took a while. 12:16:20
20 It took the summer of 1994 in Anchorage, Alaska. 12:16:23
21 Fortunately, it did not go into the winter, but it occurred 12:16:29
22 in three phases, a single jury. And the parties, after 12:16:34
23 much wrangling and multiple status conferences, and lots of 12:16:39
24 heats and eventually some light, were able to agree on a 12:16:43
25 specific trial plan for the three-phase trial of that case 12:16:46

1 which we have not submitted to the Court but can do so. 12:16:50
2 And, ultimately, based on submissions from the parties made 12:16:54
3 in the course of the trial, the Court crafted three special 12:16:59
4 verdict forms which we can likewise submit to the Court. 12:17:02

5 They were Rule 39 Special Verdict Interrogatories forms. 12:17:06
6 Phase I was the special verdict dealing with negligence, 12:17:12
7 recklessness and cause, and the jury found the Defendants 12:17:21
8 were negligent, they were reckless and their conduct caused 12:17:24
9 the harm. 12:17:28

10 Special verdict for Phase 2, compensatory 12:17:30
11 damages, was a 13-page special verdict form with 140 12:17:36
12 questions, more questions, I think, than a jury in this 12:17:39
13 court would be asked to answer, even in a front-to-back 12:17:42
14 trial of the economic damage refund claim. 12:17:46

15 THE COURT: In dealing with that verdict form, 12:17:51
16 I'm assuming that they had Plaintiffs on that form. 12:17:52

17 MS. CABRASER: They did not. 12:17:57

18 THE COURT: They did not? 12:17:58

19 MS. CABRASER: No. The reason for that, Your 12:17:59
20 Honor, is the post-class certification and pretrial, the 12:18:03
21 Plaintiffs organized the members of that class obtained 12:18:09
22 data on their damages, accumulated that data, presented it 12:18:17
23 to the Court, gave it to the expert economists who used 12:18:24
24 that data on both sides to opine as to the amount of damage 12:18:31
25 that had, in fact, occurred as a result of the spill, and 12:18:35

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1 that was complicated calculus, and the sides did not agree 12:18:39
2 and the percentage of that harm that was attributable to 12:18:48
3 the Defendants' conduct, and, again, a complicated 12:18:52
4 calculus, and the parties did not agree. 12:18:52

5 It looked somewhat like the damages or impact 12:18:55

6 phase of an antitrust trial, which is largely about what 12:18:58
7 the experts utilize in data, which may itself be in 12:19:00
8 dispute, to try to figure out in quantitative terms harm 12:19:03
9 that has been caused by anti-competitive behavior, 12:19:08
10 overcharging, and in this case, an oil spill that set in 12:19:13
11 motion a complex chain of events that Plaintiffs claimed 12:19:18
12 wiped out certain fisheries, reduced the market price of 12:19:23
13 different species of fish caught in different areas, and 12:19:28
14 impacted six different areas for five different species of 12:19:30
15 fish. That's a permutation of 30 fact scenarios. 12:19:35
16 Here in a compensatory phase here on the refund 12:19:44
17 claim, for example, we have two claims in that category. 12:19:47
18 We have the breach of implied warranty claim based on the 12:19:49
19 Uniform Commercial Code that has been adopted by name or 12:19:53
20 provision in all states. And the claim there is that 12:19:58
21 Baycol, which was not a breakthrough drug, which was an 12:20:00
22 unnecessary drug coming into a saturated market, which was 12:20:05
23 not effective and dangerous, was not worth its purchase 12:20:09
24 price, and that Plaintiffs are entitled to a refund in the 12:20:14
25 amount of difference between the drug's price and drug's 12:20:18

1 value. Classic breach of warranty, classic economic harm, 12:20:24
2 classic fodder for the experts looking at pricing and 12:20:26
3 purchasing data to opine and to argue about what the amount 12:20:32
4 of the refund should be. None of that has anything to do 12:20:36
5 with the individual Plaintiffs. They came in at the end of 12:20:41

6 all the upstream conduct, and they became class members by 12:20:45
7 purchasing the drug. They didn't have control over the 12:20:48
8 amount they paid, at least as far as individual bargaining. 12:20:54
9 They usually didn't have control over drug that was 12:20:57
10 prescribed to them. They took what the health plan paid 12:21:01
11 for and what the doctor prescribed. But they paid for 12:21:05
12 something that wasn't worth the price. If the jury agrees 12:21:09
13 that was true, the jury will calculate what the amount of 12:21:10
14 the refund should be. 12:21:15

15 Our second refund claim is an unjust enrichment 12:21:17
16 claim, and that's the equitable side of the refund class. 12:21:17
17 And that simply says that Defendants got something they are 12:21:23
18 not entitled to keep and should give it back. They got 12:21:25
19 profits from a drug that didn't need to be sold and that 12:21:28
20 should never have been sold, that no one should ever have 12:21:33
21 bought and paid for. That's unjust enrichment in a 12:21:35
22 nutshell. It's a uniform claim. The factfinder could be 12:21:39
23 this Court sitting on a bench trial on unjust enrichment 12:21:42
24 because it's an equity claim. And the question there is 12:21:49
25 were the Defendants unjustly enriched, weighing the 12:21:51

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1 equities, the utility of their conduct, the harm their 12:21:55
2 conduct could have caused, and how much did they make in 12:21:58
3 profit and how much of that profit should they give back, 12:22:01
4 and how should that refund be used. And that involves 12:22:03
5 experts looking at the Defendants financial records and 12:22:08

6 their profit figures, and this Court doing equity under the 12:22:11
7 circumstances. 12:22:15

8 So, certainly for the refund, a much simpler 12:22:17
9 version of the battle of the experts and the data and the 12:22:22
10 verdict form in Exxon Valdez could certainly be used. With 12:22:27
11 respect to those among the Plaintiffs whom this Court calls 12:22:34
12 to have their claims tried front to back from liability to 12:22:39
13 compensatory damages, the same type of verdict form could 12:22:43
14 be used. 12:22:47

15 On the punitive damages, having heard the 12:22:49
16 evidence, the disputed evidence about the level of harm and 12:22:51
17 the amount of compensation that Plaintiffs want, and by the 12:22:58
18 way, Your Honor, having disagreed substantially with 12:23:04
19 Plaintiffs' view of their damages, Plaintiffs asked for 12:23:07
20 nearly a billion dollars in compensatory damages in Exxon 12:23:09
21 Valdez and had experts to prove that. The jury cannot 12:23:14
22 accept that number and they are not required to. They did 12:23:18
23 their own calculations and they came up with a compensatory 12:23:23
24 award of just over \$200,000,000, an award confirmed on 12:23:27
25 appealing by the Ninth Circuit in 2001. 12:23:33

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1 The special verdict for Phase III, III is the 12:23:35
2 trial was a simpler verdict form that would be used today, 12:23:37
3 post Cooper. It awarded the Plaintiffs as a class, an 12:23:42
4 undifferentiated class, the amount of \$5,000,000,000 in 12:23:46
5 punitive damages, and that launched the appeal to the Ninth 12:23:51

6 Circuit from the Exxon Valdez trial. Not from the 12:23:55
7 structure. Not from the class certification. Not really 12:23:58
8 from any of the evidence or the way the evidence had come 12:24:02
9 in, but simply because Exxon contended that that award was 12:24:05
10 excessive in the light of all the evidence and the policies 12:24:11
11 that underlie punitive damages. 12:24:14

12 In 2001, the Ninth Circuit ultimately agreed with 12:24:19
13 Exxon on that point. The Cooper case come down on in the 12:24:22
14 meantime. The Cooper case had told the Ninth Circuit -- 12:24:27
15 Cooper, by the way, was a Ninth Circuit case that went up, 12:24:29
16 and as sometimes happens with Ninth Circuit cases, got 12:24:32
17 reversed. On remand, the Ninth Circuit -- it's a rare 12:24:37
18 occurrence, but it happened there. So, the Ninth Circuit 12:24:39
19 knew very well about de novo review of punitive damages 12:24:44
20 award and that it had that obligation in Exxon Valdez. The 12:24:48
21 Ninth Circuit could have done one of two things. It could 12:24:55
22 have recalculated the jury's award. It did not do that. 12:24:58
23 It remanded the award to the district court for 12:25:03
24 recalculation in light of the Cooper mandate and in light 12:25:06
25 of the Cooper factors, and Judge Holland's decision on 12:25:07

1 remand is the decision you have that came out late last 12:25:11
2 year. Judge Holland thought \$5,000,000,000 was still the 12:25:15
3 right number after all the calculus, reduced it to four, 12:25:19
4 recognizing he was under a mandate, and the case is now 12:25:20
5 back in the Ninth Circuit. And at some point, someone will 12:25:25

6 come up with a final number and it will be administered by 12:25:28
7 Judge Holland as a case management task. 12:25:32
8 If that process on that award has taken so many 12:25:36
9 years and resources of court time, and if the Supreme Court 12:25:41
10 now mandates that same process in any and every punitive 12:25:46
11 damages award, our concern is that because Plaintiffs have 12:25:50
12 a compelling case on punitive conduct and will be able to 12:25:54
13 persuade more than one jury to award punitive damages in 12:26:01
14 Baycol, that we will have a hundred or a thousand Exxon 12:26:07
15 Valdezes in the appellate courts of this country. And the 12:26:18
16 purposes of punitive damages, its legitimate purpose, may 12:26:18
17 be frustrated and receipt of punitive damages will be 12:26:22
18 delayed, and that alone places this Court's opportunity to 12:26:27
19 construct a trial plan that works in this case in an 12:26:31
20 entirely new light. In terms of the time and resources you 12:26:37
21 could save by adopting a trial plan procedure that answered 12:26:39
22 some or all of the Cooper questions on punitive damages for 12:26:41
23 this course of conduct in -- and this product than any 12:26:45
24 other court has had the opportunity to do. 12:26:52
25 Now, there have been other class action trials of 12:26:56

1 product defect cases. There have been other class action 12:27:00
2 trials of consumer claims. They have taken different 12:27:05
3 formats. In the Masonite litigation in the state court in 12:27:07
4 Alabama, the court certified a nationwide class on a 12:27:12
5 non-personal injury defective product claim. The masonite 12:27:19

6 exterior siding was defective and it deteriorated too soon. 12:27:23

7 Alabama does not have a choice of law doctrine 12:27:25

8 that enables it to select any particular state's law to

9 apply to nationwide claims. It lacks locus, so all states' 12:27:33

10 laws applied at that trial. 12:27:35

11 The trial judge decided to manage that case with 12:27:37

12 very complex legal issues and claimed legal variations in 12:27:40

13 this way. He said, look, this case is about a defective 12:27:45

14 product. I know no one is claiming they got hurt or 12:27:49

15 killed. But if there is nothing wrong with the product, 12:27:53

16 then you don't have breach of warranty claim, which is the 12:27:56

17 claim. Masonite was not unjustly enriched, and there is no 12:27:59

18 consumer fraud. So, let's find out if this product was 12:28:07

19 defective.

20 The various states used a total of five different 12:28:08

21 tests for defect. So the court prepared a special verdict 12:28:11

22 form and asked the jury to decide whether the Plaintiffs 12:28:14

23 met their burden of proof to demonstrate a defect on each 12:28:18

24 of those tests. The jury was not required to answer all 12:28:21

25 the questions the same way, and the jury was provided with 12:28:24

1 evidence that was relevant to each of the tests. And the 12:28:27

2 jury returned a special verdict form in Masonite finding 12:28:31

3 for the Plaintiffs on four defect tests and for the 12:28:32

4 Defendants on the remaining tests. And that told the Court 12:28:35

5 that the 37 states that used the first four tests, those 12:28:39

6 class members are defect claim. The class members in the 12:28:44
7 remaining states did not, and the Court was then able to 12:28:49
8 organize subsequent phases of the trial. The case settled 12:28:51
9 on the very eve of the second phase of the trial which was 12:28:57
10 going to determine the remaining liability and compensatory 12:29:04
11 and punitive damages issues for the class were the viable 12:29:05
12 claim. 12:29:08

13 That case was managed well. It was managed 12:29:11
14 fairly. It culminated into settlement, but not because it 12:29:16
15 was untriable. It culminated into settlement because it
16 was triable. In was triable in phases, and it gave the 12:29:22
17 parties enough information to know rationally what the 12:29:24
18 ultimate outcome might be and to comprise those claims in a 12:29:28
19 fair way. And that Court is in the midst of administering 12:29:33
20 a 20-year claims program for homeowners with siding, and 12:29:38
21 money that would have otherwise been spent in multiple 12:29:41
22 cases or proceedings is being used to fix people's homes. 12:29:43

23 The Avery case in Illinois was tried as a 12:29:51
24 simultaneous jury trial and bench trial on state law claims 12:29:59
25 of breach of contract and consumer fraud. The consumer 12:30:05

1 fraud claim was an equity claim. The Plaintiffs were 12:30:07
2 requesting restitution as they are here, disgorgement, and 12:30:11
3 the Judge dried that while the jury tried the breach of 12:30:14
4 contract claim. There was overlap of the evidence. 12:30:19

5 Some of the evidence the jury was not entitled to 12:30:22

6 see on the breach of contract claim because it had to do 12:30:25
7 with fraud, and the Judge viewed that evidence after the 12:30:30
8 jury went home for the day. So, that's how that trial was 12:30:30
9 structured. The jury came in with a special verdict on 12:30:34
10 damages. The Judge issued an order with reasons and 12:30:37
11 findings on the consumer fraud claim. And the Judge 12:30:39
12 determined punitive damages in that case under that claim. 12:30:44
13 The structure of the trial and the certification 12:30:48
14 of the nationwide class and the choice of Illinois law and 12:30:50
15 the verdict were affirmed on appeal by the Illinois Court 12:30:54
16 of Appeals, and we have cited that case in our briefs. The 12:30:59
17 matter is now before the Supreme Court of Illinois on 12:31:02
18 another issue and that issue really is, did a state court 12:31:05
19 have the right and the power to try those claims on a 12:31:12
20 nationwide class basis and to bind class members from 12:31:16
21 around the country in one proceeding. That is a question, 12:31:23
22 Your Honor, that any state court attempting to certify a 12:31:28
23 nationwide, or even a statewide class, involving 12:31:30
24 out-of-state conduct is going to face in Baycol if this 12:31:36
25 Court does not manage the class itself from a federal 12:31:39

1 courtroom where nationwide jurisdiction is unquestioned. 12:31:43
2 And I think that is another consideration which Your Honor 12:31:47
3 may properly take into account, and we urge should take 12:31:54
4 into account in considering the black hole and considering 12:31:57
5 what system may, with the least amount of controversy and 12:32:02

6 constitutional challenge, best and most comprehensively 12:32:07
7 adjudicate common questions. You could leave it to the 12:32:12
8 state courts. They can try class actions. As Masonite and 12:32:16
9 Avery demonstrated, they have tried nationwide product 12:32:22
10 defect and consumer class actions. And those trials, while 12:32:27
11 they have resulted in relief or been affirmed on appeal, 12:32:32
12 have been and are increasingly controversial and Congress 12:32:36
13 may soon put an end to that opportunity. 12:32:39

14 So, this litigation, though it's based on state 12:32:43
15 law claims, but there is no federal question, may not only 12:32:47
16 have its least controversial and most appropriate home 12:32:51
17 only, but, perhaps, it's only home in this courtroom. 12:32:57

18 There are other variations on the trial plan 12:33:00
19 themes that I have addressed, and we would be happy to 12:33:06
20 provide even more detail. I think, though, that if you 12:33:10
21 imagine for a moment that there is no Rule 23, let's wipe 12:33:15
22 it off the books. It's a troublesome rule and it causes 12:33:21
23 people to get upset, and it seems so sectarian. Plaintiffs 12:33:24
24 have one view and Defendants have another. 12:33:32

25 If we wipe it off the books and we were left with 12:33:34

1 the joinder rules, Rules 18 through 21, and the 12:33:37
2 consolidation Rule 42 and Rule 16, as Professor Miller 12:33:40
3 suggests, and we have in this court what we actually do 12:33:46
4 have today, a very large group of Minnesota-filed cases of 12:33:51
5 which this Court has original jurisdiction, a very large 12:33:54

6 group of cases coming in from other jurisdictions which the 12:33:59
7 parties may agree that this the Court can and should try, 12:34:02
8 and you didn't have Rule 23, and you didn't have a choice 12:34:05
9 about aggregation because aggregation had occurred and 12:34:07
10 aggregation was here, and these claims weren't going 12:34:11
11 anywhere else, certainly the Minnesota claims weren't, like 12:34:16
12 it or not, arrogant trial plan or not, specific guidance 12:34:18
13 from the manual for complex litigation or not, we would 12:34:26
14 have all to figure out how to try those case. And I would 12:34:26
15 suggest, as I did and as Professor Miller did, that what a 12:34:31
16 trial would probably look like without Rule 23 would be a 12:34:35
17 consolidation, would be an initial phase with common 12:34:40
18 issues, would be reliance on joining the parties as 12:34:43
19 parties, and not class members, to bind them to the outcome 12:34:50
20 of those special verdicts and those judgments and a hope 12:34:54
21 that collateral estoppel would work to bind, or at least 12:34:59
22 persuade or influence those not parties whose claims were 12:35:04
23 on unfiled or filed in other courts. 12:35:10

24 If you look at it in that perspective, what you 12:35:19
25 suddenly see is the only thing that Rule 23 adds to that 12:35:19

1 equation, and it's a big thing, is that it provides a way 12:35:24
2 to add people into that inevitably process, the trial that 12:35:27
3 must occur, when their numbers are too large to guarantee 12:35:33
4 that their joinder as named Plaintiffs would be 12:35:37
5 practicable. It's joinder plus. It's adding a level and 12:35:40

6 order of magnitude of benefit from the process. There are 12:35:46
7 concerns that would not exist with all the parties here by 12:35:49
8 name. 12:35:53

9 This Court could forego Rule 23 and, in effect, 12:35:53
10 create an opt-in class by issuing invitation for people to 12:35:57
11 join up for trial purposes to have their common issues 12:36:03
12 tried in this court, and large part of the good that Rule 12:36:07
13 23 does can be accomplished in that way. But it's 12:36:10
14 makeshift and it's unnecessary because we have Rule 23 and 12:36:14
15 it's incomplete. And that's really at the end of the day 12:36:17
16 the primary reason and, in fact, the only reason why we say 12:36:22
17 as Plaintiffs that some form of class proceedings, some 12:36:24
18 gathering of common issues is superior to the other 12:36:28
19 alternatives that the federal rules make available to us 12:36:35
20 all. There is not a fool-proof, bullet-proof, tailor-made 12:36:37
21 trial plan appended either to the manual for complex 12:36:47
22 litigation or the federal rules of civil procedure that we 12:36:52
23 can simply put this case caption on and use tomorrow for 12:36:56
24 trial. But the makings of it are there. We can learn from 12:36:59
25 other trials. We can see what worked. We can look at 12:37:06

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1 verdict forms, and we can look at the facts that must be 12:37:09
2 proved in this case and the issues that are really involved 12:37:12
3 far simpler than most mass torts. 12:37:14

4 Finally, just a couple of words about the refund 12:37:18
5 class. We've really simplified that claim. We only have 12:37:22

6 two claims in the master complaint that relate to the 12:37:27
7 refund remedy, the implied warranty and unjust enrichment, 12:37:30
8 and we have reduced the consumer claims to those 12:37:37
9 essentials. We could have asserted state consumer claims. 12:37:40
10 We gave Your Honor some materials on those in the event 12:37:43
11 that anyone wanted to consider adding those claims in. But 12:37:47
12 every state has the UCC, even Louisiana by another name. 12:37:50
13 Every state has it verbatim. Every state has same the 12:37:54
14 remedy for breach of warranty. Some statements require 12:37:59
15 privity 16 or 17. We have identified those for the Court. 12:38:06
16 That's a common question. Is there privity in this case 12:38:07
17 because the doctors are agents of the Defendants? Maybe. 12:38:11
18 Maybe in some categories that's true. That's a categorical 12:38:16
19 questions. If privity is required and is not present and 12:38:18
20 the jury answers, yes, it's required, and, no, it's not 12:38:22
21 present, then we know whose states residents have a viable 12:38:27
22 implied warranty claim. It really is that simple. 12:38:33
23 Is this about what people thought Baycol could 12:38:33
24 do? Is this about the fact that some people were fortunate 12:38:37
25 enough not to get injured. Not an implied warranty. 12:38:42

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1 Defendants have suggested that our Plaintiffs' claims 12:38:44
2 aren't typical because they don't have personal injuries. 12:38:47
3 There is no personal injury requirement for an implied 12:38:53
4 warranty claim. Implied warranty is about economic loss. 12:38:54
5 In drug cases where no one is injured, the consumers bring 12:38:58

6 implied warranty claims because the drug was not worth what 12:39:02
7 was charged either because of an antitrust violation, over 12:39:08
8 charge or because the drug did not do what it was claimed 12:39:12
9 to do. We gave the Your Honor the Cardizem CD antitrust 12:39:17
10 litigation cites on motion to dismiss and on class 12:39:18
11 certification. And the claim there was unjust enrichment 12:39:22
12 by people from ten different states, including Minnesota. 12:39:25
13 And on the motion to dismiss, as well as the motion for 12:39:31
14 class certification, the Cardizem found that unjust 12:39:34
15 enrichment is a universal claim . It is essentially 12:39:37
16 uniform, certainly, in all ten states surveyed by that 12:39:40
17 court in a survey far more detailed than the survey we 12:39:43
18 gave, Your Honor, from our advocate's perspective, and far 12:39:54
19 more detailed than the arguments Defendants made, three 12:39:54
20 pages in F.Supp.2d, comparing the language and the elements 12:39:54
21 of the unjust enrichment claim in all of those states. It 12:39:59
22 is uniform. 12:40:00

23 More to the point, the Cardizem court said it's a 12:40:01
24 class-wide remedy. It belongs to the class as a whole. 12:40:05
25 It's going to be granted or not. It's going to be 12:40:09

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1 calculated with respect to the class as a whole. It's 12:40:12
2 based on the Defendant's conduct and the value of the drug 12:40:16
3 and what's there. 12:40:19

4 Cardizem was a drug case. It was a hypertension 12:40:21
5 drug and the claim is there was Cardizem that makers 12:40:26

6 conspired with others to keep generics off the market and 12:40:29
7 the kept the price too high. And if consumers had had a 12:40:37
8 free and informed choice, they would have bought less 12:40:40
9 expensive drugs. Here we have Baycol entering the market. 12:40:43
10 It's low priced. It's an unnecessary drug, and siphoning 12:40:46
11 purchasers away from other, safer and more effect drugs. 12:40:50
12 That's what the evidence suggests. Now, we say that is as 12:40:53
13 much an unjust enrichment claim and, indeed, breach of 12:40:55
14 implied warranty claim as the situation where a drug price 12:41:00
15 is hyped up or the Centroid case where a brand name drug 12:41:08
16 manufacturer claimed the generics weren't as good and kept 12:41:13
17 consumers from buying cheaper drugs. Here it was Baycol 12:41:18
18 that we claim wasn't as good. Same situation. Some 12:41:23
19 experts need to come in and some factfinder, this Court or 12:41:27
20 jury, needs to decide whether Baycol was worth what was 12:41:32
21 charged for it, whether the price was manipulated unfairly, 12:41:36
22 whether consumers have a refund remedy. 12:41:42
23 That claim is really the tail wagging dog in all 12:41:45
24 of this, Your Honor. You know, when people have been hurt 12:41:49
25 and killed, it's hard to come and wave the flag and make 12:41:50

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1 policy arguments and get really worked up about a 12:41:53
2 money-back claim because the refund class members in the 12:41:55
3 very real sense are the very lucky ones. But they do have 12:42:00
4 the right to that recovery if they can prove their case. 12:42:05
5 The proof is all the Defendants' conduct. It's all 12:42:09

6 upstream. There is no reliance requirement on either 12:42:11
7 claim. There is nothing subjective about it. It's 12:42:18
8 objective. It's market forces. It's reasonable consumer. 12:42:20
9 That's where those claims live, and that's why commentators 12:42:24
10 and courts alike say those consumer claims are ultimately 12:42:29
11 suited for class treatment. They don't get brought 12:42:32
12 otherwise. 12:42:36

13 We're not representing the health plan who's here 12:42:36
14 who's brought their refund claims to this Court and who are 12:42:40
15 negotiating settlements to get money back from the 12:42:41
16 Defendants. We represent the people who cannot do that 12:42:47
17 alone, and we represent them as a class because that's the 12:42:52
18 only way that claim gets before this Court. 12:42:55

19 By the way, Your Honor, we know this is not a 12:42:57
20 limited fund case, at least not yet, but you can say in a 12:42:58
21 sense that the refund claimants are competing with the 12:43:05
22 wrongful death claims and the injury claims and the medical 12:43:11
23 monitoring claims for a share of either a finite or even an 12:43:16
24 infinite pie.

25 How better to achieve proportionality, justice 12:43:19

1 and fairness to everyone in every category than to have the 12:43:23
2 determinations of liability and damages made in a single 12:43:28
3 court under the supervision of a single Judge sitting in 12:43:31
4 equity on the unjust enrichment claim and the medical 12:43:37
5 monitoring claim to make sure that everyone is treated 12:43:42

6 fairly and there is a sense of proportionality among the 12:43:45
7 payments to people in those category because, again, to the 12:43:50
8 extent that this Court decides not to manage that claim, to 12:43:55
9 aggregate that claim, to have that claim's value 12:44:00
10 determined, to administer a remedy in this court. Other 12:44:04
11 courts may, other courts will and there is no way to build 12:44:10
12 equity from the bottom up. 12:44:13
13 The Seventh Circuit has told us in Firestone use 12:44:16
14 the market model on whether or not you can use your claims, 12:44:20
15 go file a bunch of cases, have a bunch of trials, and at 12:44:22
16 the end of day, we will probably know what that trial is 12:44:27
17 worth or everybody will be to bored or broke to care. But 12:44:30
18 economics drove the conduct that with we claim is the wrong 12:44:36
19 doing here, and the market model caused the harm and the 12:44:43
20 market model can't be relied on to generate justice, and it 12:44:47
21 can't be relied on to give equity. The courtroom is not a 12:44:53
22 marketplace. The courtroom is a hallowed place, and it's 12:44:59
23 the one place where the alleged exuberance of the marketing 12:45:03
24 force behind Baycol can be moderated and can be corrected 12:45:12
25 to put those who were only economically damaged back in the 12:45:17

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1 position they were originally in. 12:45:22
2 Perhaps to provide some of the refund remedy to 12:45:26
3 be used for medical monitoring for those same consumers, to 12:45:31
4 do them some good and to protect their health as they 12:45:36
5 thought the drug they bought would have done itself. This 12:45:42

6 Court cannot only create economies of scale, this Court can 12:45:45
7 do justice in a way that separate courts in separate 12:45:50
8 individual cases, or even multiple class actions never 12:45:57
9 could. And that is the great and unique opportunity we 12:45:59
10 believe that justifies working through some of the complex 12:46:02
11 and daunting management challenges and procedural 12:46:08
12 challenges presented by the aggregation and trial of our 12:46:12
13 claims. Thank you. 12:46:15

14 THE COURT: Thank you. We'll take a luncheon 12:46:19
15 break and we'll start up at quarter to two. 12:46:21

16 (Noon recess.)

17 THE COURT: Good afternoon Mr. Beck. 13:52:18

18 MR. BECK: Good afternoon, Your Honor. May I 13:52:20
19 proceed? 13:52:30

20 THE COURT: You may. 13:52:30

21 MR. BECK: Your Honor, Mr. Zimmerman began today 13:52:32
22 with some remarks in which he cited a famous quote from 13:52:34
23 Bobby Kennedy, and I remember hearing that same quote 13:52:38
24 during a memorial service for Senator Wellstone, and the 13:52:45
25 familiar quote ended with the phrase, "I dream of things 13:52:51

1 that never were and asked why not." And that is certainly 13:52:56
2 a noble sentiment, particularly for United States Senators 13:52:58
3 and candidates for President of the United States because 13:53:03
4 one of the things that they do is they enact laws, amend 13:53:07
5 laws and change laws. But a District Court's role, 13:53:13

6 generally speaking, is to apply the laws that have been 13:53:17
7 enacted by people like Bobby Kennedy and Paul Wellstone. 13:53:21
8 And the District Court's role is generally not to dream up 13:53:26
9 laws and procedures that never were. And the District 13:53:31
10 Court's role is generally not to order procedures and laws 13:53:35
11 that never were. And make no mistake about it, Your Honor, 13:53:41
12 certifying the classes that have been requested by the 13:53:45
13 Plaintiffs here, given the circumstances of these cases, 13:53:47
14 which I will describe in a moment, truly would be to order 13:53:50
15 things that never were. 13:53:56

16 And one of the things that Bobby Kennedy 13:53:58
17 cautioned in his quote was that if you are going to dream 13:54:03
18 of things that never were, you ought to ask why not, 13:54:08
19 because sometimes there is a good reason that things never 13:54:13
20 were. Because sometimes the thing that's being proposed 13:54:18
21 and that never has been adopted before is a real bad idea. 13:54:21
22 And sometimes the things that never were violate the rules 13:54:28
23 that have been enacted by public servants who are charged 13:54:34
24 with the responsibility for formulating those rules. And 13:54:38
25 sometimes the things that never were would work serious 13:54:42

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1 injustices without achieving offsetting savings of money 13:54:46
2 and time. 13:54:50

3 But the theme that Mr. Zimmerman set about 13:54:51
4 dreaming things that never were carried over, I think, 13:54:56
5 throughout much of the presentation by the Plaintiffs. 13:55:00

6 Really, when you read the briefs or you listen today, one 13:55:09
7 is left with the suggestion from the Plaintiffs that this 13:55:11
8 Court should not be too persnickety about the requirements 13:55:16
9 of Rule 23 and should not hold them too closely to those 13:55:22
10 requirements. 13:55:28

11 Professor Miller, for whom I have the greatest 13:55:29
12 regard, spoke about philosophy and elasticity and really 13:55:33
13 ended up articulating a philosophy of elasticity when it 13:55:40
14 came to his approach towards the requirements of Rule 23. 13:55:43

15 And in the briefs that the Plaintiffs have filed 13:55:47
16 they cite several times the general exhortation at the 13:55:50
17 beginning the rules to secure the just, speedy and 13:55:54
18 inexpensive determination of every action. And it seems to 13:55:57
19 be the rule that they rely on primarily. And it's a very 13:56:01
20 important, rule but it's a general exhortation that does 13:56:06
21 not trump the specific requirements set forth for class 13:56:09
22 actions. Indeed, the specific requirements and 13:56:15
23 prerequisites that they are required to meet reflect the 13:56:24
24 rules drafters' conclusions about how to implement that 13:56:24
25 general exhortation about just, speedy and inexpensive 13:56:27

1 resolution in the complicated context of a class action. 13:56:33

2 Rule 23 incorporates not just the goals of speed 13:56:38
3 and inexpensiveness, but also the very first goal as 13:56:45
4 mentioned in Rule 1, and that is justice. Because no 13:56:53
5 matter how speedy it might be or inexpensive from the point 13:56:55

6 of view of Plaintiffs class action lawyers, concerns with 13:56:59
7 justice dictate that Defendants not be subjected to the 13:57:06
8 threat of massive liability in collective cases where 13:57:11
9 individual issues of law and fact overwhelmingly dominate 13:57:14
10 and are intertwined with whatever common issues they are 13:57:19
11 able to identify. 13:57:23

12 But even if we set aside concerns about justice 13:57:27
13 and fairness in cases like that, the class action lawyers 13:57:30
14 that you have heard from today are simply wrong when they 13:57:34
15 claim that certifying these classes would achieve speedy 13:57:38
16 and expensive determination of the Baycol cases. When they 13:57:44
17 make those representations to you, Your Honor, I think they 13:57:49
18 ignore two key realities of these cases. 13:57:52

19 Reality number one, and well look at some 13:57:59
20 evidence from the doctors of the class representative in a 13:58:00
21 little bit to confirm this, but reality number one, is that 13:58:05
22 for the vast, vast, vast majority of people who took 13:58:10
23 Baycol, the drug worked perfectly. Cholesterol was 13:58:16
24 lowered. They are protected from heart disease, and they 13:58:23
25 suffered no side effects. For a small percentage, people 13:58:27

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1 suffered some side effects, and for an even smaller 13:58:33
2 percentage of those, they suffered some serious injuries. 13:58:37
3 So, reality number one is that for the vast majority of the 13:58:41
4 people, the drug worked perfectly, and it is a tiny 13:58:46
5 percentage who were injured. 13:58:51

6 Reality number two is that for that tiny 13:58:55
7 percentage -- 13:58:58
8 THE COURT: When we are talking about the vast 13:58:58
9 majority, what percentage. 13:59:01
10 MR. BECK: You know, Judge. 13:59:03
11 THE COURT: Guesstimate. I'm not going to hold 13:59:04
12 to you it. I'm trying to get -- 13:59:08
13 MR. BECK: In terms of Rhabdo cases, I think we 13:59:10
14 have how many Rhabdo cases that have been filed? 13:59:14
15 THE COURT: I think the numbers that I've seen, 13:59:17
16 the percentages that you have given me are about 12 percent 13:59:20
17 of the cases that have been filed. 13:59:22
18 MR. BECK: But that's 12 percent of the cases 13:59:26
19 that have been filed are Rhabdo cases. That's 7,000 people 13:59:28
20 who filed cases. There are 900,000 people we heard today 13:59:32
21 who took Baycol. 13:59:39
22 THE COURT: I understand that. I'm saying when 13:59:40
23 you say vast majority, what is your best guesstimate. 13:59:43
24 MR. BECK: I think it's well over 99 percent, but 13:59:48
25 I don't have a statistical analysis -- 13:59:53

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1 THE COURT: Again, I'm not going to hold it to 13:59:56
2 you and print it anywhere. I just want a feel for what you 13:59:56
3 think the universe is. 14:00:01
4 MR. BECK: Yes. That's a ballpark field for what 14:00:03
5 I think the universe is. So, we're talking about these 14:00:06

6 classes. If you put them altogether, of course, they 14:00:10
7 include all 900,000 people or so who took Baycol would be 14:00:13
8 in probably two or more of the classes. 14:00:19

9 Now, so, reality number one is huge numbers of 14:00:24
10 people for whom the medicine worked just fine and a tiny 14:00:29
11 number of people who had actual significant injuries. 14:00:34

12 Reality number two which they don't seem to be 14:00:38
13 able to come to grips with is that the people with the 14:00:40
14 actual injuries, the serious injuries, are going to opt out 14:00:43
15 of this class action if it's certified and pursue their own 14:00:50
16 claims. That's what they are doing now by way of their own 14:00:54
17 individual lawsuit. 14:00:57

18 People who have real injuries, and thankfully 14:01:01
19 there were few, but there were some, people who have real 14:01:04
20 injuries by in large are represented by experienced and 14:01:10
21 skilled trial lawyers who are pursuing their claims right 14:01:13
22 now in state courts, Texas, Alabama, Mississippi, Illinois, 14:01:17
23 Oregon and California and who want to pursue their claims 14:01:22
24 in federal courts, wants the remand to take place. But 14:01:24
25 these experienced trial lawyers, when representing people 14:01:29

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1 with real injuries, are not going to have their clients' 14:01:32
2 claims determined in a class action trial, tried by class 14:01:36
3 action lawyers in Minnesota. That is a reality staring us 14:01:39
4 in the face, and it's an important driver here. 14:01:43

5 Going down the path that has been urged today by 14:01:47

6 the class action lawyers is not going to lead to the just, 14:01:52
7 speedy and inexpensive resolution of the Baycol cases if 14:01:59
8 you take them as an overall problem. It's not going to 14:02:03
9 lead to any kind of resolution of that overall problem. 14:02:07
10 The overall resolution is likely to be driven by the 14:02:10
11 outcomes of individual negotiations over settlements and 14:02:14
12 trials where the people who were really injured see what 14:02:21
13 their cases are worth, and those who weren't really injured 14:02:26
14 but hoped to cash in, see what the juries think about their 14:02:31
15 cases. And that's what's going to drive the ultimate 14:02:37
16 resolution. 14:02:41

17 Meanwhile, Your Honor, I really believe that if 14:02:41
18 you follow the path that's being urge on you today by my 14:02:45
19 brothers from the other side, you would put at risk the 14:02:49
20 significant accomplishments that this Court has already 14:02:53
21 made and is in a position to make in terms of how MDLs 14:02:56
22 ought to be managed. I believe, and I think this view was 14:03:02
23 shared by members -- all the members of both the defense 14:03:08
24 team as well as the Plaintiffs' team that this MDL has been 14:03:08
25 a -- as close to a model of efficiency as one could come. 14:03:13

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1 And we would like to pretend that we share in some of the 14:03:18
2 credit, but it's largely driven and mainly driven by Your 14:03:23
3 Honor. 14:03:28

4 The discovery in this case, while people on 14:03:28
5 different sides have occasional complaints, the discovery 14:03:31

6 has been handled with genuine dispatch when you compare how 14:03:36

7 things have gone in other cases. 14:03:39

8 One of the I think striking accomplishments of 14:03:43

9 the Court has been your ability to secure cooperation from 14:03:47

10 state court judges and even most of the state court 14:03:51

11 lawyers. I remember early in the case we had threats of 14:03:54

12 competing and inconsistent and incompatible discovery 14:04:00

13 programs that were going to be imposed down in Texas and 14:04:06

14 Pennsylvania and around the country. I remember when we 14:04:11

15 then convened in Louisiana in New Orleans where Your Honor 14:04:16

16 was hoping to calm the waters and secure some cooperation, 14:04:22

17 that's the last time I had the honor of sharing a 14:04:26

18 microphone with Professor Miller, and I find him here again 14:04:29

19 today. I hope he doesn't get any aches and pains. I might 14:04:35

20 have to cross examine him again, soon. 14:04:39

21 But we were down in Louisiana and Your Honor and 14:04:43

22 Professor Miller was helping out. The focus was on 14:04:46

23 exploring ways that federal and state judges can cooperate 14:04:50

24 with one another and can accommodate one another instead of 14:04:54

25 worrying about turf fights. I think that this Court has 14:04:58

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1 made other efforts in terms of almost a national road show 14:05:05

2 and creating a State Liaison Committee with the state trial 14:05:09

3 court lawyers, and the result, I think, has been a model of 14:05:14

4 cooperation and coordination between this Court supervising 14:05:18

5 all the federal cases and the state court judges. 14:05:24

6 Even in the next couple of weeks or months, we 14:05:27
7 are going to have a series of depositions of our top 14:05:30
8 executives from Germany that are going to be held in 14:05:37
9 London. We are going to be having coordinated schedules 14:05:37
10 and agreed on procedures, not just from the lawyers in this 14:05:39
11 proceeding, but from the lawyers in all the state court 14:05:44
12 proceedings. And all of this, Your Honor, has required a 14:05:47
13 lot of patience, diplomacy on your part, and I would 14:05:49
14 suggest even a dosage of humility. Your Honor did not go 14:05:55
15 down to New Orleans and declare there is a new sheriff in 14:05:59
16 town and everybody is going to do it your way. It was 14:06:03
17 exactly the opposite. 14:06:07
18 I believe that that spirit of cooperation and 14:06:08
19 accommodation is going to be genuinely endangered if you go 14:06:12
20 along with what will be perceived by state court trial 14:06:16
21 judges and state court trial lawyers as a power grab by the 14:06:20
22 federal class action lawyers. 14:06:28
23 It's going to be much harder to secure 14:06:29
24 cooperation, either by you or the next Judge who has an 14:06:34
25 MDL. If the state court judges and the state court trial 14:06:36

1 lawyers say, gee whiz, there was all this great talk about 14:06:40
2 how we were going to be respected and our prerogatives are 14:06:43
3 going to be respected, and the next thing you knew, we had 14:06:47
4 a class action, a nationwide no opt-out class, trying 14:06:51
5 issues like punitive damages and medical monitoring, issues 14:06:53

6 that we considered to be central to the public policy of 14:06:59
7 our states. And not only is it swept into a class action, 14:07:02
8 but people can't opt-out, and this federal judge in 14:07:05
9 Minnesota tells me that I don't get to try those cases. 14:07:10
10 Whether you are a trial lawyer or a trial judge in these 14:07:13
11 states, I think that's going to be a serious concern. 14:07:18
12 And I think that, Your Honor, instead of the kind 14:07:21
13 of cooperation and accommodation that you have encouraged 14:07:24
14 and achieved in this MDL so far, the likely result of 14:07:28
15 certifying the kind of classes they want you to certify 14:07:35
16 would be -- we would revert to what I think as the Oklahoma 14:07:37
17 land rush style of litigating these cases where it's a mad 14:07:42
18 race to the courthouse to see who can impose the most 14:07:48
19 onerous discovery schedule soonest, who can get their cases 14:07:53
20 to trial soonest so they can hold themselves out as the guy 14:07:58
21 who can deliver the bucks and can sign up on the cases from 14:08:06
22 around the country. And those races, Your Honor, are 14:08:11
23 always won by local lawyers who are in local jurisdictions 14:08:13
24 where the courts are going to be especially accommodating 14:08:17
25 to them for whatever reasons. Those races are never won by 14:08:20

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1 MDL judges who have broader responsibilities to federal 14:08:25
2 courts throughout the country to get their cases ready in 14:08:31
3 an orderly way so that they can be remanded. 14:08:35
4 So, I think these practical considerations that 14:08:38
5 I've outlined, I genuinely believe these are very real 14:08:41

6 considerations, and I think that when contemplating what 14:08:44
7 kind of philosophy, as Professor Miller suggested you ought 14:08:47
8 to bring to this, those are factors that I would suggest 14:08:52
9 the Court might want to consider. 14:08:58

10 Now, why is it -- 14:09:01

11 THE COURT: Before you go on, without the 14:09:01
12 cooperation of both sides, this MDL would not be moving in 14:09:04
13 the way that it's moving. I can't take all the credit for 14:09:13
14 it. I just want to make sure that the record is clear that 14:09:22
15 without the Plaintiffs and the defense being cooperative 14:09:27
16 and bringing issues to the Court to understand that state 14:09:31
17 court issues and in allowing the Court to reach out to 14:09:39
18 state trial judges and also the state trial lawyers, we 14:09:45
19 would not be where we are at today. And, certainly, you 14:09:51
20 know that other defense counsel in other cases have taken 14:09:57
21 the scorch the earth policy. And if you had taken that 14:10:02
22 position, the Court would not have been able to do 14:10:12
23 anything. 14:10:12

24 I want to make sure the record is clear that 14:10:12
25 without the cooperation of both sides, we would not be 14:10:15

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1 where we are at today. It's very important that you 14:10:17
2 understand that. I understand that and I appreciate that. 14:10:21

3 And, also, again, as I've stated all the time, 14:10:25
4 what I want is a fair administration of justice in this 14:10:31
5 case and I want to seriously hear what you have to say and 14:10:35

6 the responses from Plaintiffs on what you are putting 14:10:43

7 forth. 14:10:49

8 One other issue dealing with the state court 14:10:50

9 lawyers. As you well know, there are going to be lawyers 14:10:55

10 that are going to go out and try the cases no matter what, 14:11:05

11 and you have that situation in Texas now. 14:11:08

12 MR. BECK: In fact, I pick a jury a week from 14:11:10

13 Monday. 14:11:12

14 THE COURT: That's right. Let's see where we go 14:11:12

15 with that. 14:11:18

16 MR. BECK: I appreciate the Court's comments. I 14:11:19

17 think that certainly on behalf of the defense counsel, we 14:11:23

18 appreciate the comments and we share the Court's 14:11:26

19 appreciation for how the Plaintiffs' counsel helped to move 14:11:35

20 this along and secure the cooperation from the state arenas 14:11:41

21 as well. 14:11:46

22 My point is that even with all the goodwill that 14:11:46

23 I think we have assembled in this room, if we didn't get a 14:11:51

24 pretty healthy dose of cooperation and accommodation from 14:11:55

25 the other side, from the state court side, we'd be in a 14:12:00

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1 heck of a mess. And my concern, Your Honor, is that 14:12:04

2 notwithstanding the continued goodwill that you will get 14:12:10

3 from all sides in this case, no matter how this matter of 14:12:12

4 class certification is resolved, it's going to have an 14:12:17

5 impact in the state courts and with the state court trial 14:12:21

6 judges. And it's also going to have an impact, Your Honor 14:12:24
7 I know that you are concerned with this, but the next MDL 14:12:29
8 that comes along. Even if you are not blessed with this 14:12:33
9 responsibility, some other poor judge is going to be, and 14:12:36
10 if he tries or she tries to duplicate Your Honor's 14:12:42
11 accomplishments in terms of achieving that level of 14:12:46
12 cooperation, it's going to be an awful lot harder if those 14:12:49
13 same judges who showed up at the New Orleans conference are 14:12:54
14 saying to themselves, yeah, this sounds great, and the last 14:13:00
15 time I was asked to cooperate and I did not put my cases on 14:13:03
16 the super fast track, and I didn't accommodate my state 14:13:07
17 trial lawyers who wanted to get to trial right away, a year 14:13:12
18 later the federal judge took away the cases from my lawyers 14:13:15
19 here in Harris County. And he said that punitive damages 14:13:19
20 are not going to be tried in Texas or Illinois or West 14:13:24
21 Virginia. Punitive damages could be tried by a judge or a 14:13:29
22 jury up in Minneapolis. That's not the way we do things in 14:13:39
23 Texas. I'm going to risk that again. I'm going to impose 14:13:39
24 my own schedule. People are going to live by my schedule, 14:13:41
25 and my case are going to go to trial first. 14:13:44

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1 That's really what we heard back in Louisiana 14:13:47
2 from the Pennsylvania judge, as I recall. He talked about 14:13:51
3 how his were going to go first and, in fact, I think he was 14:13:52
4 brought into the fold and the schedule had been coordinated 14:13:54
5 reasonably well. I think it's a different story if that 14:13:58

6 judge who is in charge of complex litigation in 14:14:03
7 Philadelphia, Pennsylvania, which is a big center for state 14:14:06
8 court complex litigation, if he gets it in his head that 14:14:11
9 the next time I cooperate with a federal judge, then he's 14:14:15
10 going to turn around some months later and certify a no 14:14:21
11 opt-out nationwide class on causes of action that we here 14:14:24
12 in Philadelphia think are awfully important and under our 14:14:28
13 state public policy. 14:14:34

14 So, I throw that out, Your Honor, because I think 14:14:36
15 they are important considerations to the administration of 14:14:38
16 justice that go beyond these particular classes and even go 14:14:43
17 beyond this particular case. But I think that they're the 14:14:47
18 types of things that Your Honor would at least like to 14:14:50
19 consider. 14:14:52

20 Now, why is it that a state court lawyer, or for 14:14:53
21 that matter, a lawyer who's got a federal case that was 14:15:00
22 MDLed, perhaps against her will, and she's waiting for the 14:15:04
23 case to get prepared and remanded, why is it that they as 14:15:11
24 well as Defendants would view these certification of the 14:15:16
25 classes that they have asked for as basically a power grab 14:15:20

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1 by the class action lawyers. 14:15:27

2 Well, we think this situation with these 14:15:28
3 circumstances that I'm going to talk about is a classic 14:15:31
4 situation where individual questions of facts predominate 14:15:35
5 over and are inextricably intertwined with whatever common 14:15:40

6 questions of fact that can be identified. We also believe 14:15:47
7 that individual questions of law predominate over and are 14:15:50
8 inextricably intertwined with any common issues of law. I 14:15:56
9 note in this regard, Your Honor, that most of the legal 14:16:00
10 issues that we talk about concern state laws, and as I 14:16:03
11 alluded to earlier, these are state laws on matters that 14:16:08
12 touch on very important issues of state public policy. 14:16:11

13 It's also a classic situation, Your Honor, where 14:16:16
14 no matter what the outcome of the kind of common issue 14:16:21
15 trial that they are hypothesizing, the ball would not be 14:16:27
16 significantly advanced toward an ultimate resolution of the 14:16:32
17 Baycol product. 14:16:36

18 Now, let me turn to some of those circumstances. 14:16:40
19 I'm going to be discussing some facts today, but I want to 14:16:42
20 pause for a moment and just comment briefly Mr. Arsenault's 14:16:48
21 presentation of the facts. He spent twenty minutes or so 14:16:57
22 weaving together an excellent story from the Plaintiffs' 14:17:00
23 point of view. Of course, there are evidentiary fragments 14:17:15
24 that he takes, and you can imagine that if I were to give 14:17:15
25 an opening statement I would have some answers to many of 14:17:17

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1 the points that he made. 14:17:20

2 Most of the facts that he talked about were 14:17:20
3 geared to the underlying -- to the merits of the underlying 14:17:25
4 case to show Your Honor, or to hope to persuade Your Honor 14:17:27
5 that they had a real strong case on the merits. As I'm 14:17:33
6 sure Your Honor appreciates, we have a different view as to 14:17:38

7 many of those fact issues. I am not going to spend my time 14:17:43
8 today, however, going through a rebuttal of those or trying 14:17:46
9 to put our context on the facts that he went through. 14:17:50
10 Instead what I'm going to do is I'm going to review some 14:17:52
11 facts that Bayer directly on class certification, rather 14:17:56
12 than on whether they think they could win in a trial 14:18:01
13 against us. And the kinds of facts that I'm going to 14:18:04
14 review are, first, undisputed historical events when labels 14:18:08
15 changed and when new doses were approved. So, a simple 14:18:15
16 timeline of key chronological events. And the second thing 14:18:19
17 I'm going to be taking a look at is what the Plaintiffs 14:18:26
18 lawyers themselves say about the nature of their claims and 14:18:29
19 how they think they are going to prove those claims, 14:18:32
20 because that's a pretty good indication about whether in a 14:18:36
21 real life trial common issues or individual issues are 14:18:40
22 going to end up predominating. So, I'm going to be 14:18:46
23 spending time on those kinds of facts. 14:18:49
24 Before I do, I want to pause and deal with a few 14:18:53
25 what I think of as threshold legal issues that when I 14:18:57

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1 thought about the organization of this, I just thought I 14:19:00
2 need to get these out of the way sooner rather than later 14:19:04
3 because otherwise it's going to be too disruptive to the 14:19:07
4 presentation. So, let me deal first with some of these 14:19:11
5 legal points. 14:19:15
6 I think everyone understands that in a trial of a 14:19:16

7 real life person's case, issues of causation, fact of 14:19:21
8 injury and damages are going to be key components. And I 14:19:30
9 believe that the Plaintiffs' lawyers have conceded that 14:19:36
10 individual causation, in other words, did they cause Mrs. 14:19:41
11 Withers any harm. And an injury, what was the harm, if 14:19:48
12 any, caused by Baycol, and the extent of damages. All of 14:19:57
13 those by their nature individual issues and not susceptible 14:20:01
14 to a common trial. 14:20:06

15 These are the types of issues that most courts 14:20:08
16 agree predominate over the sort of common issues that they 14:20:11
17 try to identify, and they are the kinds of issues that most 14:20:17
18 courts agree render class trials unmanageable because they 14:20:21
19 are going to be intertwined, even if they don't 14:20:31
20 predominate. 14:20:31

21 Now, the Plaintiffs' lawyers have tried to get 14:20:33
22 around this problem of these kind of overarching, highly 14:20:35
23 individual questions. They've tried to get around that 14:20:40
24 problem in a couple of different ways. 14:20:44

25 The first way I call the slice and dice approach. 14:20:46

1 What they've tried to do is they take the case and then 14:20:49
2 they slice off all of the issues that they have to agree 14:20:52
3 are individual issues. And then they are left with a tiny 14:20:56
4 slice, sort of from the end of the sausage, but then they 14:21:02
5 say here on this slice of the case we found some common 14:21:06
6 issues that we think can be segregated. And on this little 14:21:10

7 slice of the sausage, the common issues predominate. And, 14:21:15
8 Your Honor, we think that that approach to defining whether 14:21:22
9 common or individual issues predominate is incorrect and 14:21:26
10 impermissible. 14:21:32

11 We believe that the law is that you look at the 14:21:33
12 case as a whole and as it exists in real life, and you say, 14:21:35
13 do common issues predominate this real life case, or do 14:21:40
14 individual issues predominate this real life case. You do 14:21:44
15 not slice away all the individual issues and then say, have 14:21:49
16 I carved out an artificial piece of the case where I can 14:21:53
17 say common issues predominate. 14:21:58

18 We have a cite from the Castano case on this 14:22:03
19 point. This is the Castano opinion. It's the kind you get 14:22:05
20 off the internet rather than F.2d. So, if you turn over to 14:22:16
21 Page 14 of the opinion, what I'm going to be focusing in, 14:22:24
22 if I can blow it up a little bigger, is this footnote, 14:22:30
23 where the Castano court, the Fifth Circuit, tobacco case in 14:22:35
24 1996, said, "severing the defendants conduct from 14:22:40
25 reliance," that's what was involved there, "under Rule 23 14:22:46

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1 (c)(4) does not save the class action. A district court 14:22:48
2 cannot manufacturer predominance through the nimble use of 14:22:52
3 Subdivision (c)(4). The proper interpretation of the 14:23:00
4 interaction between Subdivisions (b)(3) and (c)(4) is that 14:23:02
5 a cause of action as a whole must satisfy the predominance
6 requirement of (b)(3) and that (c)(4) is a housekeeping 14:23:09

7 rule that allows courts to sever the common issues for 14:23:10

8 class trial." 14:23:15

9 So, this is the approach that we think reflects 14:23:17

10 the law, and that is, Your Honor, you have to decide the 14:23:20

11 case as whole do common issues predominate. If they do, 14:23:24

12 then it's okay under (c)(4) as a housekeeping matter to 14:23:31

13 sever those predominant common issues for a separate trial. 14:23:35

14 But what you don't do is slice it up artificially and then 14:23:41

15 say walla, I found myself a case suitable for class action. 14:23:44

16 Now, the second way that the Plaintiffs' lawyers 14:23:54

17 try to get around the fact that the case really is 14:23:59

18 characterized by individual issues such as causation, 14:24:02

19 injury and damages, the second way they try to get around 14:24:08

20 that is through their sort of shifting positions as to 14:24:12

21 choice of law. When I was reading the briefs recently, I 14:24:18

22 was struck at the metamorphosis of their position. I guess 14:24:22

23 times change in Professor Miller's words, and here the 14:24:26

24 Plaintiffs started out by saying that the law of 14:24:30

25 Pennsylvania should govern all of their causes of action 14:24:32

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1 against Bayer, or as Plan B, the law of Connecticut should 14:24:38

2 govern all of their causes of action against Bayer. And 14:24:45

3 somebody along the line may have figured out that that may 14:24:50

4 have created problems for them because we know from 14:24:53

5 subsequent briefs that under the law of Pennsylvania, there 14:24:57

6 is no strict liability for pharmaceutical products. So, 14:25:01

7 that would not be a good thing for that cause of action 14:25:06
8 that they. 14:25:09
9 And, also, under the law of Pennsylvania, the 14:25:09
10 refund theory that was discussed right before lunch has 14:25:13
11 been rejected. Meanwhile, Plan B, the law of Connecticut, 14:25:19
12 Connecticut rejects medical monitoring as a cause of 14:25:24
13 action. 14:25:28
14 So, as the Plaintiffs said, their initial view 14:25:31
15 was Pennsylvania or Connecticut, but they said further 14:25:33
16 discovery might persuade us that the laws somewhere else 14:25:39
17 might be more appropriate. This case may have been 14:25:41
18 discovery of the law rather than discovery of the facts, 14:25:45
19 but in later briefs, we stopped hearing about Pennsylvania 14:25:48
20 governing all their causes of action or Connecticut 14:25:55
21 governing all their causes of action. And, instead, they 14:25:59
22 seem to be fighting the battle now on the battle ground of 14:26:01
23 saying, okay, 51 states, 50 states plus the District of 14:26:06
24 Columbia, but we can do it with 51 states. We can have a 14:26:14
25 manageable, sensible class action trial under the laws of 14:26:18

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1 51 states, don't be scared by 51 states. And their 14:26:20
2 rationale there is that, well, the law, while there are 51 14:26:24
3 states, the law really is pretty uniform and whatever minor 14:26:29
4 differences exist in the laws of the 51 states can be taken 14:26:33
5 care of through mechanisms such as special verdict forms 14:26:36
6 and jury instructions. 14:26:43

7 Now, Your Honor, I'm going to spend some time on 14:26:49
8 this because I think, and those of us on the defense team 14:26:50
9 are very firmly convinced about this that the existence of 14:26:55
10 the controlling laws from 51 different jurisdictions is an 14:26:59
11 insurmountable barrier in this case to class certification. 14:27:04
12 I want to use as an example one of the questions that would 14:27:09
13 come up in any kind of trial, including one of their 14:27:13
14 hypothesized class issues trials. And that would be 14:27:20
15 whether we conform to the state of the art in our design 14:27:32
16 and manufacture of Baycol. So, state of the art will 14:27:32
17 likely come into play, at least under the laws of some 14:27:36
18 states. It's an issue that -- it's not a cause of action, 14:27:40
19 obviously, but it's an issue that's kind of a mix of fact 14:27:44
20 and law that would be relevant, depending on whose law 14:27:49
21 applies to a negligence cause of action, to a strict 14:27:54
22 liability cause of action, to a failure to warn cause of 14:28:01
23 action and under punitive damages. I have a slide that 14:28:05
24 illustrates this. 14:28:10

25 This is a slide where we just pulled together a 14:28:13

1 summary of the state of the art analysis under the laws of 14:28:17
2 a few of the 51 states. In Colorado and Kentucky the plans 14:28:24
3 with the state of the art sets up a presumption that the 14:28:31
4 defendant was not neglect or strictly liable. Of course, 14:28:35
5 like all were presumptions, they can offer evidence to try 14:28:40
6 to rebut it. So, we would have that presumption in our 14:28:45

7 favor under the law of those two states. 14:28:48
8 In Georgia and Indiana, it's the defense to 14:28:51
9 liability. In Missouri, it's a defense to failure to warn 14:28:56
10 case. In California it can be used to prove the lack of 14:29:00
11 the kind of state of mind that's necessary to impose 14:29:04
12 punitive damages. In Arkansas and Illinois, the court say 14:29:08
13 that a jury can consider it. But in Arkansas, they say 14:29:12
14 that the state of art has to be determined from the date 14:29:18
15 the product was put on the market, not the date on which 14:29:21
16 the plaintiffs sustained an injury. And that can vary from 14:29:26
17 state to state. In Montana, state of the art evidence is 14:29:30
18 actually part of the plaintiff's case in chief rather than 14:29:37
19 defendant's defense. 14:29:42

20 In some states, our examples are Rhode Island and 14:29:45
21 Vermont, the courts have not yet determined whether state 14:29:48
22 of the art evidence is admissible or not or for what 14:29:52
23 purpose. 14:29:57

24 And then, of course, in Hawaii and Pennsylvania, 14:29:57
25 it's reversible error for the jury to consider evidence on 14:29:59

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1 the state of the art. 14:30:04

2 Here we have one that's state of the art and our 14:30:09
3 jury here of Minnesotans is going to have a verdict form 14:30:12
4 and jury instructions that say, well, the Plaintiffs have 14:30:15
5 to prove it for this state, the defendants have to prove it 14:30:18
6 for -- I'm going it make up the states -- the defendants 14:30:23

7 have to prove it in California, the plaintiffs have to 14:30:25
8 prove it in Wyoming. And then defendants prove it in 14:30:29
9 Arkansas is relevant to one cause of action and not 14:30:35
10 another. In California, only if we're talking about 14:30:38
11 punitive damages. And when you get to Hawaii and 14:30:41
12 Pennsylvania, put it out of your mind because it's 14:30:44
13 reversible error for you to even have heard any evidence 14:30:46
14 about it. So, that's one example of how confounding the 14:30:55
15 problems would be if we try to have any sort of liability 14:30:57
16 trial under the laws of 51 jurisdictions. It's not the 14:31:03
17 only example. 14:31:08
18 There'll be questions whether our product was 14:31:11
19 unreasonably dangerous. I think one of the lawyers this 14:31:15
20 morning said that they would be able to prove to this 14:31:18
21 Minnesota jury that our product was unreasonably dangerous. 14:31:22
22 But whether our product was unreasonably dangerous is 14:31:30
23 subject to legal tests. Some of them are set forth in 14:31:36
24 statute. Some are set forth in judicial decisions. Others 14:31:37
25 are set forth in pat jury instructions. 14:31:42

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1 Again, we have only taken a sampling of this 14:31:45
2 case. In Missouri there is no tests. In Arkansas and 14:31:49
3 Wisconsin, they have what they call the ordinary consumer 14:31:53
4 test. And I think it was Ms. Cabraser who said on issues 14:31:56
5 like this, it's just the objective, you know, reasonable 14:32:01
6 man or something. Maybe she is right under some of the 14:32:04

7 states. But here's what the states themselves say. 14:32:07
8 Arkansas and Wisconsin, ordinary consumer. Whereas, in 14:32:11
9 Kentucky it's not the consumer at all. It's ordinary, 14:32:16
10 prudent manufacturer tests. In California and Alaska, it's 14:32:19
11 a two-prong test, and I confess as I sit here right now, I 14:32:27
12 can't remember either prongs. But there are two prongs in 14:32:29
13 those states. 14:32:32

14 In Oklahoma, a jury has to look at the 14:32:33
15 subjective knowledge and expectation of the consumer who 14:32:36
16 would be foreseeably expected purchase the product. That's 14:32:41
17 their particular formulation.

18 Alabama is whether the consumer ought to have 14:32:48
19 reasonably anticipated the danger. In New York and Florida 14:32:51
20 there is a risk benefit analysis. So, people are 14:32:57
21 instructed you have to look at the risks that are posed by 14:33:02
22 the product, but you also have to look at the benefits 14:33:03
23 derived that are from the product. 14:33:05

24 In Idaho the question is is there a defect that 14:33:06
25 boils down to that. And in our old friend Pennsylvania and 14:33:09

1 in West Virginia, it's reversible error to instruct the 14:33:14
2 jury on the meaning of unreasonably dangerous. 14:33:21

3 So, again, you'd have the preposterous situation 14:33:26
4 where if we only take these states on the question of 14:33:29
5 unreasonably products, you'll get conflicting and 14:33:35
6 inconsistent instructions for 10 states. And then when you 14:33:37

7 get to Pennsylvania and West Virginia, you say put it out 14:33:41
8 of your mind because you are not allowed to consider any 14:33:45
9 instruction at all on what unreasonably dangerous means. 14:33:49
10 The last example that I want to discuss in this 14:33:56
11 regard, Your Honor, is punitive damages. The practice in 14:33:59
12 Minnesota, as Your Honor knows quite well, is that a 14:34:05
13 plaintiff is not even allowed to plead punitive damages 14:34:09
14 without leave of court after making a threshold showing. 14:34:12
15 The Plaintiffs' lawyers, they are like me, they are from 14:34:19
16 around the country and not all of them are well versed in 14:34:22
17 Minnesota law, and, so, they overlook this requirement, and 14:34:26
18 we had scheduled for today this hearing on whether you are 14:34:32
19 going to certify a class for punitive damages, and they 14:34:35
20 have forgotten to seek to amend their pleadings to ask you 14:34:40
21 for permission to include a punitive damages claim. 14:34:45
22 I raise that not to tease them, because the truth 14:34:47
23 is, Judge, I probably would have forgot too, and it's not 14:34:52
24 that big a deal, but what it does underscore is that 14:34:56
25 Minnesota takes seriously how it handles punitive damages. 14:35:01

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1 This is -- it's a snafu in this case that can be overcome, 14:35:05
2 and we are not going to stand on ceremony. But it reflects 14:35:12
3 a serious public policy in Minnesota about the extent to 14:35:17
4 which punitive damages are appropriate, whether they're 14:35:19
5 going to be allowed even to be pleaded until the somebody 14:35:24
6 can make a threshold showing. And Minnesota is not the 14:35:27

7 only state in America that cares deeply about how punitive 14:35:30
8 damages are handled. Other states feel like they have a 14:35:38
9 big stake in this issue as well. 14:35:40

10 So, we have different rules, then, on punitive 14:35:43
11 damages and how they are handled in different states. And 14:35:48
12 you know, we can do a fifty-state survey on the thing, but, 14:35:52
13 happily, with power point you are kind of forced to limit 14:35:57
14 it to a small enough handful and they fit on one page. 14:36:02

15 Pennsylvania -- I keep talking about Pennsylvania 14:36:07
16 because once upon a time, their Plaintiffs' lawyer said 14:36:07
17 they wanted everything resolved in Pennsylvania. In 14:36:12
18 Pennsylvania on punitives, juries may consider things such 14:36:15
19 as the character of the defendant's acts, the nature and 14:36:18
20 extent of the harm to the plaintiff, and the wealth of the 14:36:22
21 defendant. It would be of hard, incidentally, under 14:36:25
22 Pennsylvania law and the kind of trial that's being 14:36:31
23 hypothesized by the Plaintiffs to get any kind of punitive 14:36:34
24 damages judgment or assessment or special verdict that 14:36:41
25 would mean anything since they are carving out the nature 14:36:44

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1 and extent and the harm to the Plaintiffs. 14:36:50

2 Pennsylvania jurors are -- I shouldn't say 14:36:54
3 Pennsylvania jurors, a Minnesota jury applying Pennsylvania 14:36:59
4 law are entitled to consider that if it's not going to be 14:37:00
5 in this case. 14:37:06

6 In New York, juries are allowed to consider the 14:37:08

7 wealth of the defendant. They are told they don't have to, 14:37:13

8 but they can. 14:37:17

9 In California, they must consider the wealth of 14:37:17

10 the defendant. And if the plaintiff forget to put in that 14:37:21

11 evidence, they lose. So, we are going to have an jury 14:37:23

12 that's told that you can consider it when you answer this 14:37:32

13 is question, you must consider it when you answer this 14:37:37

14 question. California punitives are not allowed in wrongful 14:37:42

15 death actions. They purport to represent people who died 14:37:48

16 from Baycol. And in California, at least, they are not 14:37:50

17 allowed to have punitives. 14:37:53

18 And, then, in Connecticut the jury decides 14:37:54

19 whether to give punitive damages, and the court has to 14:38:00

20 decide the amount, but it can't be more than twice the 14:38:04

21 compensatories. Then, they've got a whole bunch of 14:38:06

22 variations as you go from state to state. 14:38:10

23 Even the Plaintiffs' cases, by and large, the 14:38:12

24 cases that they rely on recognize that punitive damages are 14:38:15

25 not appropriate for class-wide treatment. They are not 14:38:18

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1 asking you here to dream of things that never were because 14:38:23

2 there are some isolated examples. Judge Weinstein, most 14:38:30

3 notably out of New York, who has certified a punitives 14:38:35

4 class. We believe that Judge Weinstein in this instance is 14:38:40

5 way outside the stream of normalcy on punitive damages and 14:38:44

6 class actions. We think that his order, which he -- my 14:38:54

7 understanding of the procedural situation, is that the 14:38:59
8 defendants have sought an immediate appeal. The Plaintiffs 14:39:06
9 have agreed that an immediate appeal is appropriate, and 14:39:11
10 Judge Weinstein has agreed that an immediate appeal is 14:39:14
11 appropriate. And the papers have been filed and have been 14:39:18
12 sitting up there in the Second Circuit for quite some time, 14:39:20
13 so everybody is kind of waiting for the other shoe to drop. 14:39:27
14 In any event, we think that here, even if Your 14:39:31
15 Honor were persuaded by Judge Weinstein's analysis in that 14:39:38
16 case, and that case, Your Honor -- well, that analysis 14:39:42
17 would not apply here. 14:39:44
18 In the Simon case that Judge Weinstein did this 14:39:46
19 in, and it's a tobacco case is what he calls a mature tort. 14:39:49
20 There have been lots and lots of verdicts around the 14:39:55
21 country including lots of verdicts for punitive damages. 14:39:59
22 There is some concern that he expressed that money could 14:40:01
23 run out and people who might be entitled to an award of 14:40:05
24 punitive damages won't get any because punitive damages 14:40:09
25 would have been awarded to so many other people in so many 14:40:13

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1 other cases based on the proven track record in the tobacco 14:40:16
2 litigation. And, so, he created basically a limited fund 14:40:25
3 for punitive purposes. 14:40:27
4 Here we have a much different situation. No 14:40:29
5 matter what the Plaintiffs say, you know, they are 14:40:32
6 advocates and they're ethically bound to make the best case 14:40:33

7 they possibly can on behalf of their real clients as well 14:40:38
8 as their punitive clients, but he we have immature tort. 14:40:43
9 We have one that's about as immature as you can get. There 14:40:48
10 is not a single decision out there anywhere that says 14:40:52
11 anything about liability, anything about causation, 14:40:55
12 anything about damages, anything about punitive damages. 14:40:59
13 So, we don't have the kind of track record, years of 14:41:02
14 experience that Judge Weinstein was looking at. Nor do we 14:41:05
15 have any assertion, much less a showing that Bayer would 14:41:10
16 not be able to satisfy any awards that the Plaintiffs 14:41:13
17 reasonably could expect. 14:41:18

18 In this respect, Your Honor, we think the case is 14:41:18
19 quite similar to the Paxil case that was decided recently 14:41:23
20 by Judge, I think her name is pronounced Pfaelzer, in the 14:41:29
21 Central District of California. Let me just put up an 14:41:34
22 excerpt from that. 14:41:40

23 There we go. I'm going to have to read from two 14:41:56
24 pages, so let's see if I can do a split screen here. Yes, 14:42:03
25 okay. Bear with me for just a second, Judge. Here we go. 14:42:08

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1 So, we were at the bottom of Page 30, over to the 14:42:33
2 top of Page 31, and this is commenting on the approach that 14:42:37
3 Judge Weinstein took in deciding the case. "For the sake 14:42:46
4 of its analysis, the Court assuming without in any way 14:42:51
5 suggesting that the theory adopted in Simon II is a viable 14:42:54
6 one. Even with this assumption, the Court must decline 14:43:00

7 Plaintiffs' invitation to certify a limited fund class 14:43:02
8 here. Initially, Plaintiffs failed to demonstrate that 14:43:07
9 they would be entitled to a punitive damages award. Before 14:43:13
10 certification on the basis of a punitive damages cap, the 14:43:14
11 Court must scrutinize whether the Plaintiffs here have a 14:43:18
12 legitimate chance of, one, recovering punitive damages, 14:43:22
13 and, two, large enough to breach the punitive damages cap. 14:43:26
14 As a result of extensive discovery and numerous previous 14:43:32
15 trials, the Simon court had available such evidence 14:43:35
16 suggesting that punitive damages might be available. No 14:43:38
17 such evidence or arguments are advanced by plaintiffs." 14:43:38
18 Now here we have a lot of talk about punitive 14:43:43
19 damages, but we're not trying the case on the merits, and 14:43:46
20 we don't have the kind of track record that was pointed out 14:43:49
21 as the present in the Simon case. 14:43:53
22 And, then, further down, let me just get rid of 14:43:58
23 these and go on Page 31. This applies quite directly here. 14:44:06
24 The Judge continues, "Furthermore, the method in which 14:44:18
25 Plaintiffs propose to try the case would not solve the 14:44:22

1 problem that Simon II contemplates." Remember Simon was 14:44:26
2 contemplating a problem where, gee whiz, the tobacco 14:44:30
3 companies might run out of money to pay punitive damages, 14:44:38
4 so some people who might otherwise be able to collect are 14:44:41
5 going to be going to be left without a punitive award, so I 14:44:45
6 need to gather all the money in my courthouse to figure out 14:44:49

7 how to pass it out. 14:44:58

8 Says, "Furthermore the method in which the 14:44:58

9 Plaintiffs propose to try the case does not solve the 14:45:00

10 problem that Simon II contemplates. By trying each case 14:45:03

11 separately, each Stage 2 jury would have no idea how 14:45:07

12 another jury was awarding to other class members. Thus, no 14:45:11

13 jury would possess the knowledge necessary to determine 14:45:15

14 what the overall punitive damages should be and how those 14:45:15

15 damages should be applied to the different classes. The 14:45:16

16 overall cap might, thus, exceed any Constitutional cap." 14:45:21

17 Your Honor, this type of criticism applies to two 14:45:27

18 out of the three ways that the Plaintiffs have suggested 14:45:30

19 you could deal with punitive damages in a class trial. One 14:45:34

20 of the ways that they suggested is we're just going to ask 14:45:37

21 a jury of Minnesotans to give us a multiplier or a ratio. 14:45:45

22 We're going to convene this jury and we're going to try the 14:45:53

23 case and then we're going to stand over there and look at 14:45:55

24 those friendly faces in the jury box, and we're going to 14:45:57

25 say, we'd like to you fill out a verdict that says whatever 14:46:00

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1 damages anybody gets across the country will be multiplied 14:46:03

2 times three, eight, whatever, a multiplier. And then, 14:46:08

3 according to the Plaintiffs, all the lawyers from around 14:46:15

4 the country can put that multiplier in their pocket and 14:46:21

5 their entitlement to punitive damages and go back to 14:46:28

6 Homewood, Illinois, try their case and then put that on the 14:46:30

7 table and get their multiplier. Well, if they did that, 14:46:35
8 then there is no cap. The whole rationale from Simon II, 14:46:40
9 or one of the rationales, was that the Constitution as 14:46:43
10 interpreted in Cooper says that at some point there has to 14:46:49
11 be a cap. 14:46:53
12 Well, getting a multiplier to an open-ended 14:46:54
13 number of verdicts with open- ended potential actual 14:47:00
14 damages does not achieve that. So, their first way would 14:47:03
15 fail. 14:47:07
16 The second way that they have suggested is that, 14:47:08
17 well, we won't have multiplier, we won't have dollars, 14:47:10
18 we'll just have determination that punitives are 14:47:16
19 appropriate. And, then, the lawyers can bring that back to 14:47:19
20 their home court and they'll have res judicata in their 14:47:24
21 favor that punitives are appropriate. 14:47:28
22 But once again, that doesn't accomplish the 14:47:34
23 goal -- and we think that Judge Weinstein was really 14:47:36
24 reaching outside where he should have been here. But at 14:47:39
25 least he had a coherent theory of needing a cap. That 14:47:42

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1 wouldn't accomplish any sort of cap. All that does is make 14:47:47
2 it easier for people to get punitive damages all around the 14:47:50
3 country. It's going to result in unlimited punitive 14:47:55
4 damages, not some sort of constitutionally acceptable cap. 14:47:57
5 The third approach that they have suggested is, 14:48:03
6 well, let's create a limited fund here in Minnesota where 14:48:06

7 we're going to try the case to a Minnesota jury and we're 14:48:11
8 going to say to the Minnesota jury, you tell us the 14:48:16
9 aggregate amount, the total amount you think is right for 14:48:19
10 the punitive damages, and that would be the punitive 14:48:24
11 damages award, then we'll divvy that up later among people 14:48:28
12 who want in on the action. 14:48:32

13 The problem there is that while you would have a 14:48:35
14 cap, you would have a cap if, in fact, people from around 14:48:37
15 the country had any respect for that cap which I will get 14:48:44
16 to in a second. But for the class members, at least, I 14:48:47
17 guess, you would have a cap. But the problem with that 14:48:50
18 approach is that you'd run afoul of the requirements in 14:48:54
19 Cooper that punitive damages bears some relationship to the 14:48:58
20 harm actually caused. Do you remember these cases? I 14:49:03
21 can't actually remember the names of these cases, but you 14:49:09
22 get these crazy cases where somebody has got a scratch on 14:49:11
23 their BMW and it's a 150 bucks to fix it and there's 14:49:22
24 \$500,000,000 or something in punitive damages, and the 14:49:22
25 courts say from a Constitutional point of view, that's out 14:49:24

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1 of whack. There has to be some sensible proportionality. 14:49:30
2 Well, just coming up with a number which is then 14:49:34
3 going to be divvied up by the class action lawyers, and 14:49:36
4 they are going do decide which of their Plaintiffs get how 14:49:39
5 much, doesn't respect that Constitutional requirement. 14:49:42
6 A couple of final points on punitive damages. 14:49:46

7 Ms. Cabraser was talking about the Cooper case, and 14:49:50
8 basically was suggesting that Cooper has federalized the 14:49:54
9 standards for punitive damages. Now, after Cooper, there's 14:50:01
10 just three questions that you have to ask in any punitive 14:50:05
11 damages case, and it doesn't matter whether it's here in 14:50:09
12 federal court in Minnesota or down in Nueces County, Texas 14:50:14
13 where I will be confronting this issue in about a week. 14:50:19
14 Incidentally, Judge, if you're going to take punitive 14:50:23
15 damages away from all those state court lawyers, I take it 14:50:26
16 as a personal favor if you do it within the next five days. 14:50:31
17 But Ms. Cabraser the incorrect. In fact, what 14:50:36
18 Cooper did was it set Constitutional limits on what states 14:50:40
19 are allowed to do. States retain the ability to have their 14:50:44
20 own unique approaches to when punitive damages are 14:50:50
21 appropriate and the factors that could be considered and 14:50:53
22 the amounts that can be appropriate. And then superimposed 14:51:01
23 on top of the state procedures are the Constitutional 14:51:05
24 limits that they can't go beyond. 14:51:09
25 So, just because Cooper said that there are 14:51:11

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1 Constitutional limits beyond which states cannot go, that 14:51:14
2 doesn't mean that the only question in any state in the 14:51:19
3 union on punitive damages are those three Constitutional 14:51:24
4 limits that you read. That's just not the law. 14:51:29
5 Lastly, on this idea of a limited fund, the 14:51:36
6 limited fund works only if it is a no opt-out class, 14:51:39

7 because otherwise we've got all these thousands of people 14:51:50
8 who are pursuing their claims in state courts already and 14:51:54
9 others, represented by some lawyers in this room, who at 14:51:59
10 the first opportunity want to try their case in federal 14:52:03
11 court back in Los Angeles, who are not going to be all that 14:52:07
12 keen on being a part of a class. They're going to want to 14:52:11
13 try their own case and put in all the glory evidence and 14:52:16
14 make the best use they can of it because they thing they 14:52:23
15 are really good lawyers and they can make win more money 14:52:23
16 doing it their way than they can if the class action 14:52:23
17 lawyers do it for them here in Minnesota. And any notion 14:52:30
18 that this limited fund is going to hold up and is going to 14:52:32
19 cap punitive damages, I think is awfully ambitious 14:52:37
20 thinking. And, in fact, I think I can predict with a high 14:52:42
21 level of confidence that that would be attacked like crazy 14:52:47
22 by members of the Plaintiffs' bar, both from the state 14:52:52
23 court side as well as from the federal court side. 14:52:55

24 THE COURT: Well, at some point, address the 14:53:01
25 issue that happened in Indianapolis dealing with Firestone. 14:53:05

1 They won the issue there. 14:53:14
2 MR. BECK: I didn't. 14:53:17
3 THE COURT: I know. I said they won the issue 14:53:17
4 there and came back to the court and tried to enjoin the 14:53:19
5 court from allowing anything to happen in state court. 14:53:25
6 MR. BECK: Your Honor, I would like to come back 14:53:28

7 to that, I'm sure that at some point during my remarks we 14:53:29
8 are going to take a break, and I'd like to be able to 14:53:37
9 organize my thoughts on that and respond to it after our 14:53:39
10 first break, if I could. 14:53:43

11 THE COURT: Yes. 14:53:44

12 MR. BECK: The Plaintiffs also have suggested, 14:53:48
13 Your Honor, some alternatives to a nationwide class. And I 14:53:52
14 think that these alternatives that they have suggested, 14:53:59
15 basically, for this Court to try statewide class would be 14:54:02
16 unworkable for the same reasons that we are going to be 14:54:09
17 going through concerning the nationwide class. 14:54:13

18 Rule 42, for example, does not work to create a 14:54:17
19 common issue trial unless you really have workable common 14:54:23
20 issues. In fact, it ends up being similar to Rule 23. If 14:54:27
21 you've got individual issues of fact and law that overwhelm 14:54:35
22 the common issues, a Rule 42 approach is not practical. 14:54:40

23 Here, of course, they have not given the Court 14:54:48
24 any kind of coherent plan to proceed under Rule 42 any more 14:54:50
25 than they have given a coherent plan on how they would plan 14:54:57

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1 to proceed under Rule 23. They just said that somehow they 14:55:00
2 will come up with a plan, but we haven't seen one. 14:55:05

3 In terms of the proposed statewide class, there 14:55:08
4 was mention that maybe Your Honor could have a trial that 14:55:14
5 would just be the Minnesota claimants, people who filed 14:55:17
6 their cases here in Minnesota, and -- or Professor Miller 14:55:20
7 suggested that maybe you could have a trial here in 14:55:26

8 Minnesota for the, I think he said 3,000 cases that are 14:55:30
9 pending in federal court in Pennsylvania that have been 14:55:36
10 transferred here. 14:55:42
11 A couple of problems. One is there are by our 14:55:42
12 count over 800 cases that have been filed in federal court 14:55:49
13 in Minnesota that are part of this proceeding. Twenty-four 14:55:54
14 of the 800 were filed by people who live in Minnesota. 776 14:56:02
15 were filed as diversity claims by people who live in 14:56:16
16 Pennsylvania, Illinois, Oklahoma, Arizona, Hawaii, etc., 14:56:19
17 etc., etc. So a class trial of the Minnesota claimants, 14:56:24
18 the people who filed case in Minnesota, is going to be a 14:56:29
19 trial concerning the laws of 51 states. 14:56:34
20 Similarly, Professor Miller said, well, there are 14:56:38
21 those 3,000 cases pending in Pennsylvania, I haven't gone 14:56:42
22 through the complaints, but through deductive reasoning, 14:56:47
23 I've figured out the number of Pennsylvania plaintiffs and 14:56:50
24 those federal Pennsylvania cases is zero or close to it. 14:56:55
25 And that is because if they were from Pennsylvania, we're 14:57:02

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1 from Pennsylvania and there wouldn't be diversity and they 14:57:05
2 wouldn't be in federal court. They would be in -- state 14:57:10
3 court. So, they have got some really good lawyers in 14:57:13
4 Pennsylvania, and a lot of people think that the 14:57:17
5 Pennsylvania federal courts are good places to try 14:57:19
6 plaintiffs' causes of action, so people come from all over 14:57:23
7 the country and file diversity actions in Pennsylvania and 14:57:27

8 venues are okay because we operate there. So, if you as a 14:57:32
9 Minnesota federal judge get a Minnesota jury to try 14:57:36
10 Professor Miller's class of Pennsylvania federal claimants, 14:57:40
11 the only law that you probably wouldn't have to apply is 14:57:46
12 Pennsylvania. So, you would have 50 jurisdictions. 14:57:49
13 Pennsylvania just wouldn't be one of them. 14:57:53
14 So, you are going to have the same problem of 14:57:56
15 defining and then applying the law of 51 jurisdictions, 14:58:01
16 whether that's on the liability issues that they identify 14:58:03
17 or on punitive damages. 14:58:07
18 Okay, so, I said I was going to talk about facts 14:58:11
19 after my brief excursion into the law. Now, I'm going to 14:58:15
20 actually do that. Your Honor, what I've got up here on the 14:58:20
21 screen is the beginnings of a timeline, and what I'm going 14:58:24
22 to show up here on the top of the timeline is whether we 14:58:29
23 came out with different doses of Baycol and then what the 14:58:37
24 different warning labels said and how they evolved over 14:58:37
25 time. So, these are the facts that I referred to earlier 14:58:41

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1 as just sort of undisputed historical events rather than 14:58:46
2 characterizations about what we knew or anything else. 14:58:51
3 So, we first came on the market in the United 14:58:56
4 States with the .2 milligram and .3 milligram doses in 14:58:59
5 September of 1997. At the time, we had what was called a 14:59:06
6 rhabdomyolysis class warning. Just for the Court's 14:59:10
7 information, we didn't have a warning at the time that said 14:59:17

8 Baycol can cause Rhabdo, and the reason is, interestingly, 14:59:23
9 when we did our clinical trials, we didn't have a single 14:59:28
10 case of Rhabdo. But we knew that Baycol is a statin, and 14:59:33
11 all statins, once they get out there beyond the clinical 14:59:39
12 trial stage and larger numbers of people take them, that 14:59:44
13 all statins, people are going to experience Rhabdo with. 14:59:48
14 So, we had a warning that said Baycol is a statin, statins 14:59:52
15 can cause Rhabdo. And there can be acute renal failure. 14:59:56
16 We also said that if you experienced muscle pain, 15:00:02
17 tenderness and weakness, talk to your doctor. So, that was 15:00:06
18 -- obviously, there was a lot of other stuff on the label, 15:00:11
19 but the key stuff for this case. That's from September of 15:00:15
20 '97, and the little pills down there, that's the .2 dose 15:00:17
21 and the .3 dose and that shows when they came out. 15:00:24
22 Your Honor, we don't have sets already prepared, 15:00:29
23 but before we leave this week, we'll give you a set of 15:00:32
24 materials that we have been showing up here. 15:00:36
25 The next label was from November of 1998, what we 15:00:40

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1 call Label No. 2. This still related to the 2 and 3 15:00:46
2 milligram doses. Here, by this time now, we have been 15:00:50
3 selling the medicine and we've got a lot larger universe, 15:00:55
4 more experience than we had just in the clinical trials. 15:01:00
5 So, just as we knew would happened and everybody in the FDA 15:01:05
6 knew and everybody knew, every doctor knew, sure enough 15:01:09
7 people take Baycol, someone is going to get Rhabdo just 15:01:12

8 like they do with Zocor and Lipitor and all the other 15:01:18
9 statins. 15:01:22
10 So, now we are able do warn specifically that 15:01:24
11 Rhabdo has been reported with Baycol and sometimes with 15:01:25
12 acute renal failure. We also noted at this point what was 15:01:32
13 an unusual situation that when people, at least the report 15:01:36
14 of Rhabdo with us, they seemed to be focused mainly where 15:01:39
15 people also were taking another drug called Gemfibrozil. 15:01:43
16 You heard about Gemfibrozil this morning, and I know you've
17 read about it in the paper -- in the papers that have been 15:01:50
18 filed. So, when people are taking what we he call Gemfib 15:01:55
19 along with Baycol, that seemed to account for a significant 15:02:01
20 percentage of the Baycol reports. And we said, if you have 15:02:06
21 any muscle pain, tenderness or weakness, talk to your 15:02:10
22 doctor. 15:02:15
23 The next label change came out in May of 1999. 15:02:20
24 That's when our .4 dose was approved by the FDA. So, this 15:02:23
25 label applied to .2, .3, and .4. It repeated the Rhabdo 15:02:30

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1 warning that Baycol had been associated with Rhabdo, 15:02:38
2 sometimes with acute renal failure. Once again, cautioned 15:02:42
3 patients that if they experienced any muscle pain, 15:02:49
4 tenderness or weakness, they should talk to their doctors. 15:02:50
5 And, then, since we had some more experience with 15:02:54
6 Gemfibrozil, the warning was beefed up somewhat and it was 15:02:59
7 explained that the combined use of Cerivastatin, that's the 15:03:03

8 non-brand name for Baycol. It's the chemical name. So, 15:03:12
9 combined use of Baycol and Gemfibrozil should be avoided 15:03:15
10 unless the benefit is likely to outweigh the increased risk 15:03:18
11 of this drug combination. So, increased knowledge is what 15:03:25
12 we have that led to an additional more elaborate warning 15:03:30
13 label. 15:03:34

14 The next label was Label No. 4. We're still now 15:03:34
15 we have .2, .3, and .4 as the doses. And now we have 15:03:41
16 what's called a Gemfibrozil contraindication. And in the 15:03:44
17 world of pharmaceuticals, a contraindication is a big deal. 15:03:50
18 Doctors understand that when something is contraindicated, 15:03:55
19 that's a stronger statement than merely a warning about how 15:03:59
20 you shouldn't use them together. Contraindication means 15:04:05
21 that it's basically off-labeled usage if you're going to 15:04:08
22 co-prescribe. 15:04:14

23 There may be a doctor out there who's got a 15:04:19
24 patient who has a condition that's such where they need 15:04:20
25 Gemfibrozil and Lipitor hasn't worked and Zocor hasn't 15:04:24

1 worked and the other statins haven't worked because each 15:04:29
2 one is a little different. That may be that a doctor makes 15:04:33
3 a medical determination that he's going to co-prescribe 15:04:34
4 even though it's contraindicated. Or it may be that the 15:04:42
5 doctor is doing a lousy job. He's not paying any 15:04:43
6 attention. That can happen, too.

7 But in any event, that's what the new label said. 15:04:46

8 And, then, of course we recorded that Rhabdo could be 15:04:50
9 associated with Baycol, sometimes with acute renal failure, 15:04:53
10 and asked to report any muscle pain, tenderness or 15:04:59
11 weakness. 15:05:04

12 We also sent out on this contraindication this 15:05:05
13 Dear HCP. That's for Dear Health Care Provider, and we 15:05:09
14 wanted to get the word out and, so, we sent out a Dear 15:05:13
15 Health Care Provider letter explaining to doctors and 15:05:18
16 clinicians and others that a majority of the Rhabdo cases 15:05:22
17 that we had seen involved patients end taking Baycol and 15:05:26
18 Gemfibrozil at the same time. 15:05:33

19 Label 5 came out in July of 2000. This was when 15:05:37
20 we introduced .8. So, .8, which you have heard a lot about 15:05:42
21 today, doesn't really come on the scene until July of 2000. 15:05:47
22 We included the Gemfibrozil contraindication, don't use 15:05:53
23 Baycol with Gemfibrozil. We once again encouraged the 15:05:55
24 people to report any muscle pain, tenderness or weakness. 15:06:02
25 We also in our Rhabdo, we had the usual Rhabdo warning, but 15:06:08

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1 we also had learned some more, and we said that it's 15:06:12
2 especially important for elderly and low body weight women, 15:06:16
3 that they were particularly susceptible here. So, we have 15:06:21
4 seen in the reports from the field that older women who 15:06:26
5 were thin seemed to be particularly susceptible, so we 15:06:31
6 included that. 15:06:34

7 We also had a recommendation. Remember, now, we 15:06:36

8 are coming out with this new dose, .8. We had a 15:06:39
9 recommendation that people start at .4. And you don't 15:06:44
10 start somebody at .8, start them at .4, and, then, if .4 15:06:46
11 isn't doing the job, then you consider taking them up to 15:06:52
12 .8. That process is called titration, Your Honor. So, we 15:06:56
13 were saying you should titrate. Start at the low does, 15:07:01
14 because .8 is powerful stuff, and only use .8 if the lower 15:07:05
15 dose isn't working. 15:07:11

16 The next label is from December of 2000. It 15:07:16
17 applies to all the doses that are out there, 2, 3, 4, 8 15:07:19
18 milligrams, and has the Gemfibrozil contraindication. 15:07:24
19 Encourages people to report any muscle pain, tenderness or 15:07:29
20 weakness. Repeats the special caution for elderly, low 15:07:34
21 body weight women. Again, it recommends starting at .4 15:07:35
22 rather than starting immediately at .8. And, then, has the 15:07:40
23 patient information sheet that went along with it. It had 15:07:46
24 all the sort of prescribed warning stuff that you have. 15:07:50
25 And then it had a patient information sheet, basically, in 15:07:52

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1 an effort to say some things and repeat some things and say 15:07:56
2 it in as direct English as we could. 15:08:01

3 We told people -- we're telling the doctors that 15:08:07
4 Gemfibrozil was contraindicated, and then we say to the 15:08:10
5 people, do not take Baycol if you're taking Lopin. That's 15:08:13
6 the brand name for Gemfibrozil. And we tell them, again, 15:08:16
7 report any muscle pain, tenderness or weakness. 15:08:20

8 Label 7, this was in May, 2001. It relates to 15:08:27
9 all of the doses. And here we are elaborating on the .4 15:08:32
10 versus .8 notion of what you should start out. And we say 15:08:39
11 in this label that beginning Baycol, that is your starting 15:08:43
12 dose, if you start Baycol above .4, that increases the risk 15:08:50
13 of myopathy and Rhabdo. So, well tell them don't do it. 15:08:56
14 Report muscle pain, tenderness and weakness which we have 15:09:02
15 said from day one, repeating about the elderly, thin women 15:09:07
16 and the patient information sheet, once again, in plain 15:09:09
17 English, don't take Baycol if you're taking Gemfibrozil. 15:09:11
18 Report any muscle pain. And then we say if you're taking 15:09:13
19 Baycol for the first, your daily dose should be .4 or 15:09:21
20 lower. Don't start at .8. We sent out a Dear Health Care 15:09:23
21 Provider stressing the same thing, .4, and this was around 15:09:32
22 the same time. .4 is the starting dose. .8 is only the 15:09:35
23 titration dose. And once again we repeated, don't 15:09:40
24 co-prescribe. Don't give your patients Baycol and 15:09:45
25 Gemfibrozil at the same time. 15:09:50

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1 Notwithstanding these efforts, people -- we were 15:09:53
2 getting reports of people who were experiencing Rhabdo. A 15:09:58
3 lot of those report, not all, by any means, a lot of the 15:10:04
4 reports were people who had been started at .8, not 15:10:08
5 notwithstanding everything we said, and people who had been 15:10:11
6 prescribed Gemfibrozil, notwithstanding everything we said. 15:10:15
7 So, after consultation with the FDA, we withdrew Baycol 15:10:19

8 from the market the first week of August of 2001. So, 15:10:24
9 that's the basic sequence of warning labels and when doses 15:10:29
10 came out. 15:10:36
11 Your Honor, just as aside, I think Your Honor 15:10:37
12 asked a question of Mr. Arsenault about when was the drug 15:10:41
13 withdrawn in England, and I think, I'm pretty confident 15:10:44
14 that the accurate response to Your Honor's question was 15:10:51
15 that in England, the authorities suspended sales of .8, but 15:10:54
16 not the other dosage -- not the other doses. That they 15:11:01
17 suspended sales of .8 about six weeks earlier than Bayer 15:11:07
18 voluntarily withdrew all Baycol from the market in the 15:11:13
19 United States. So, I think that's an accurate response to 15:11:20
20 the Court's question. 15:11:22
21 Now, I couldn't resist, and as I went along, I 15:11:27
22 did a little bit of editorializing. You could see how we 15:11:31
23 would present our case here. What I really want to spend a 15:11:36
24 little time on now is to talk about how the Plaintiffs have 15:11:40
25 presented to you today the way that they are trying their 15:11:43

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1 case and what they are going to show and why we are bad 15:11:47
2 people. And what we saw in the half an hour or forty-five 15:11:51
3 minute presentation this morning was an argument that Bayer 15:11:58
4 started off early on with these low doses based on clinical 15:12:07
5 trials, and, of course, they would say said that we did 15:12:14
6 something wrong here, but then they say, boy, it got much 15:12:17
7 worse. It got more comfortable because they started to 15:12:22

8 learn more information and started to get feedback from the 15:12:27
9 field. And notwithstanding this additional information, 15:12:33
10 they continued to sell these doses. And then they he did 15:12:33
11 some studies and other people did some studies, and they 15:12:38
12 should have known that putting .4 on the market was going 15:12:40
13 to be a bad idea. I think I got one over here. 15:12:44

14 THE COURT: In fact, you can touch the screen and 15:12:49
15 make marks on it. 15:13:01

16 MR. BECK: I feel like John Madden if I start 15:13:04
17 doing this. Here we go, when we. When I was listening to 15:13:06
18 their presentation, when you had move into the time right 15:13:12
19 before .4, they had additional information, and 15:13:14
20 notwithstanding the new information that should have 15:13:17
21 convinced them not to do it, the people came into the 15:13:21
22 market with .4. And then with .4, sure enough they gained 15:13:28
23 more information that should have told them to yank it off 15:13:35
24 the market, but they didn't yank it off the market because 15:13:39
25 they put dollars before the people, and they were working 15:13:44

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1 on .8. And at the time they were working on .8, they had 15:13:48
2 all kinds of information that should have told them not to
3 put .8 on the market, but the put it on the market anyway. 15:13:57
4 After they got .8 on the market, they got more information, 15:13:57
5 and they should have yanked it off the market sooner than 15:13:58
6 they did. And the story that we heard was one of 15:14:03
7 increasing culpability. One of more and more proof as you 15:14:07

8 go on in time that Bayer did the wrong thing. We can see 15:14:15
9 that story if we look at their pleadings. 15:14:18
10 This is from their opening brief, Page 13, 15:14:33
11 undeterred by the evidence of increased injuries at higher 15:14:44
12 doses. So, here we were, you know, we've gone past .2. 15:14:49
13 We're in the higher doses, and according to Plaintiffs' 15:14:55
14 lawyers we have evidence of increased injuries, but we are 15:14:56
15 undeterred by it, and we continue to push for FDA approval 15:15:02
16 to market Baycol at higher doses. May, 1999, four months 15:15:05
17 after 1999 required warnings changed, the FDA approved 15:15:13
18 increasing the doses from 3 to 4, despite the data from 15:15:20
19 there clinical trials blaming increased adverse experiences
20 to the high doses. The Defendants launched an advertising. 15:15:24
21 So, the idea is we knew more and more, and, yet, 15:15:26
22 we persisted in this evil scheme. I hope Your Honor 15:15:30
23 appreciates that I'm not buying into the story as I go, but 15:15:38
24 I think it's important to know what kind of case they say 15:15:41
25 they are going to put up. 15:15:45

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1 Same thing over on Page 24, bottom paragraph, 15:15:46
2 Paragraph J. Defendants seek approval, and then, Your 15:15:51
3 Honor, remember, this is not their complaint or memo for 15:15:57
4 some extraneous purpose. This is their brief explaining 15:16:09
5 why class certification is appropriate. So, when they're 15:16:14
6 telling you why the class should be certified, they say 15:16:17
7 well the facts are that despite the serious events that 15:16:22

8 occurred in the post market patient population, including 15:16:26
9 fatality reports and the sign that the drug had caused 15:16:26
10 significant cellular necrosis, particularly at higher 15:16:36
11 doses. Bayer and SmithKlineBeecham once again, sought 15:16:36
12 approval in the market, again, at even higher doses. 15:16:39
13 Now, there's a lot of facts packed in there, but 15:16:40
14 each one of them has to do with their theory that we became 15:16:42
15 increasingly culpable over time because we got post 15:16:45
16 marketing information, and we got fatality reports. We got 15:16:51
17 reports that at particularly higher doses things were bad. 15:16:55
18 And notwithstanding that, we decided to go ahead with .8. 15:16:59
19 The same theme is over on Page 17 in their brief. 15:17:05
20 I don't even have to read them. I mean you get the idea, 15:17:13
21 Judge, and all you have to do is really look at the 15:17:17
22 heading. The Defendants ignore the results of their own 15:17:20
23 testing. So, we're going to have, as you can imagine a 15:17:23
24 different factual story at trial, but that's their story. 15:17:32
25 And as I said, their story is that culpability increased 15:17:39

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1 over time. Let's see if I can go back -- back to this 15:17:45
2 timeline that I put up. 15:17:52
3 The reason I spent so much time on this, Judge, 15:17:53
4 is because Plaintiffs' own papers made clear that there are 15:17:57
5 going to be thousands and potentially hundreds of thousands 15:18:01
6 of particular, unique personal fact patterns that are going 15:18:07
7 to govern liability in this case. And that's even before 15:18:12

8 we start talking about individual causation or whether 15:18:18
9 there was injury or what the damages are. And let me -- I 15:18:21
10 can't help myself, I have to wander over here even if I 15:18:26
11 have the space-age laser beam. 15:18:30
12 If I'm a plaintiff's lawyer and I've got a case 15:18:34
13 for Mrs. Withers who started taking .2 Baycol a couple of 15:18:39
14 weeks after it came on the market and took it for 3 weeks, 15:18:46
15 and then stopped because her HMO said that they had a good 15:18:50
16 deal with the makers of Lipitor and they wanted her to use 15:18:55
17 Lipitor instead and she switched to Lipitor and she never 15:18:59
18 had any problems while she was on Baycol, and she never had 15:19:03
19 any problems when she felt on Lipitor, she's got one case. 15:19:07
20 And if I got Mr. Jones over here in June of 2001 who took 15:19:12
21 .8 Baycol for a week and got rhabdomyolysis and was 15:19:22
22 hospitalized and had to go on dialysis, he's got a 15:19:31
23 different case. It's not just a different case because 15:19:37
24 Mrs. Withers didn't suffer any injury and Mr. Jones 15:19:40
25 suffered acute renal failure. It's a different liability 15:19:44

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1 case because the facts are different as to what we knew 15:19:49
2 back in 1997 and what we were telling the medical community 15:19:53
3 back in 1997 versus what we knew in the year 2001 and what 15:19:59
4 we knew and what we were telling the medical community in 15:20:06
5 2001. 15:20:10
6 Their failure to warn case, for example, which 15:20:10
7 they say is just a simple cases, applies to everybody. But 15:20:11

8 there's a whole bunch of different warnings. There are 15:20:17
9 people who bought the drug back when Label 1 was out there, 15:20:20
10 and there are people who bought the drug when Label 6 was 15:20:24
11 out there. And those are different liability cases. 15:20:28

12 Same thing with negligent failure to warn or 15:20:32
13 negligent marketing. The drug shouldn't have been on the 15:20:36
14 market. They are going to be able to tell one story if the 15:20:40
15 real life plaintiff took the drug back in here in the early 15:20:47
16 days when what we have got are clinical trials and not a 15:20:52
17 single person experienced Rhabdo, and we have it on the 15:20:56
18 market and we are just starting to get feedback from the 15:21:00
19 marketplace as to the effects of our medicine, their story 15:21:05
20 on negligent marketing is a lot different here than it is 15:21:09
21 over there. And they're both different from even here. 15:21:18

22 In fact, what you have if you took their 900,000 15:21:18
23 plaintiffs, is you would have 900,000 bars up here that 15:21:24
24 would begin where somebody started Baycol and end where 15:21:28
25 they stopped taking Baycol. Except for some of them, there 15:21:32

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1 would be more than one bars because they would take Baycol 15:21:37
2 for a little while and then they would switch to Lipitor 15:21:40
3 and then they would switch back to Baycol. 15:21:43

4 So, we have in terms of the critical time period 15:21:46
5 to ascertaining liability under their own theory, it's 15:21:49
6 going to be different for every single plaintiff. And a 15:21:53
7 ruling as to somebody in 2001 is not going to mean anything 15:21:57

8 as to somebody in 1998 and vice versa. So, there are going 15:22:02
9 to be all these unique types. And that would be true, 15:22:09
10 Judge, even if you were going to apply the law of Minnesota 15:22:12
11 to everybody's claim because you would still have all these 15:22:14
12 individual facts in terms of, okay, failure to warn as to 15:22:19
13 what, when and what. So, those facts, individual facts, 15:22:25
14 are going to predominate even if you were to apply the law 15:22:29
15 of one state. 15:22:33

16 But, of course, what we are really going to end 15:22:34
17 up doing, is we are going 900,000 little bars up here 15:22:38
18 representing individual Plaintiffs' Baycol uses 15:22:44
19 superimposed over those 900,000 bars are the laws of 51 15:22:47
20 states, and not just the laws on 51 states just on 15:22:53
21 negligence, but the laws of 51 states on eight of ten 15:22:57
22 causes of action that they have identified. 15:23:03

23 So, understand their own theory as to why we're a 15:23:08
24 bad company, they reveal that the individual questions are 15:23:10
25 going to predominate any liability issues. 15:23:15

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1 Now, it was interesting to me that the class 15:23:19
2 action lawyers, I don't think ever mentioned once any of 15:23:22
3 the class reps. Not a single class representative was ever 15:23:27
4 alluded to or mentioned by name. So, I'm going to talk 15:23:32
5 about them instead. So, I've got a handful of the 900,000 15:23:39
6 little bars that we put up here. So, these are the little 15:23:47
7 vignettes that come along with each one -- 15:23:53

8 THE COURT: Before we move to this, it's time for 15:23:55

9 a break before my court reporter quits on me. Let's take a 15:24:00

10 15-minute break. 15:24:05

11 (Recess taken.)

12 THE COURT: Mr. Beck, you may continue. 15:43:49

13 MR. BECK: Thank you, Your Honor. Before I move 15:44:00

14 on to the individuals Plaintiffs, let me respond to the 15:44:00

15 Court's question concerning the Firestone case. Here's my 15:44:05

16 understanding of the case. I confirmed it over the break. 15:44:08

17 A district judge in Indiana certified an economic class in 15:44:10

18 the Firestone cases. He must not have been on the mailing 15:44:16

19 list for the Seventh Circuit's opinions for the last couple 15:44:24

20 of years, but he certified -- I'm sorry, she. She 15:44:32

21 certified an economic class. The Seventh Circuit, no 15:44:33

22 surprise, decertified the class and also said, don't come 15:44:36

23 back here with any statewide classes. The Seventh Circuit 15:44:41

24 said the laws would have to be under 51 jurisdictions, and 15:44:44

25 that's an insurmountable problem, but don't come back here 15:44:47

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1 asking for statewide classes because that has the same kind 15:44:51

2 of problem, and we don't want you taking up our time with 15:44:55

3 that. 15:44:58

4 So, then what happened is the Plaintiffs' lawyers 15:44:59

5 went out instead of to the district judges in Indiana, went 15:45:01

6 to state court judges around the country and sought to get 15:45:05

7 state classes certified in state courts. And then the 15:45:09

8 defense lawyers tried to use the All Writs Act and convince 15:45:13
9 the district judge that the Judge ought to enjoin the state 15:45:21
10 court class actions under the All Writs Act. The district 15:45:25
11 judge said, no, such an order will not be in aid of my 15:45:30
12 federal jurisdiction, and if you don't like the class 15:45:33
13 actions in the state courts, then go to the state court 15:45:37
14 judges and persuade them that the class actions are a bad 15:45:40
15 idea. So, the teaching of the case, Your Honor, is that 15:45:43
16 it's a good thing that the Jones Day firm is not involved 15:45:48
17 in this case. (Laughter) Now, I say that because they are 15:45:52
18 not here to defend themselves. 15:46:03
19 Your Honor, back to the timeline. I've been 15:46:06
20 talking how even if you focus solely on our conduct and the 15:46:09
21 horrible things they say about us, all that does is 15:46:17
22 underscore that individual issues predominate because this 15:46:19
23 is not a ship that sank. This is not a bad batch of 15:46:24
24 medicine that got contaminated. This is a course of 15:46:29
25 conduct over five years that under their theory, we became 15:46:33

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1 increasingly culpable. So, there is different evidence as 15:46:44
2 to whether we would be liable, depending on when the 15:46:44
3 plaintiff took the medicine. So, it's fundamentally 15:46:48
4 different from a typical mass disaster where an event 15:46:53
5 occurs in time and affects people at the same point in 15:46:59
6 time, and, perhaps, they suffered different damages, but 15:47:03
7 they were affected basically in the same way by the same 15:47:06

8 event that took place at the same time so the evidence as 15:47:09
9 to liability is going to be the same. Here, the evidence 15:47:11
10 is going to be vastly different depending on when somebody 15:47:16
11 began taking -- began taking Baycol. 15:47:19

12 So what I want to do now is go through some of 15:47:28
13 these individuals, and we've got them organized by color. 15:47:31
14 There are three classes that the Plaintiffs have been 15:47:35
15 talking about. The red individuals are the class 15:47:38
16 representatives that they have identified in the personal 15:47:43
17 injury class. So, the people who they claim actually were 15:47:47
18 injured by taking Baycol. The purple people are the class 15:47:52
19 representatives for the medical monitoring class that they 15:48:01
20 want certified. And then the green people are the class 15:48:06
21 representatives for their refund class. And what I want to 15:48:09
22 do is spend a few moments on each one of these class 15:48:15
23 representatives because when we look at their story, we see 15:48:18
24 that no matter what might -- no matter what one might think 15:48:23
25 about common issues versus individual issues, focusing only 15:48:31

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1 on Bayer, once you include the other parties to the 15:48:35
2 litigation, the plaintiff, because after all the other 15:48:39
3 parties are the Plaintiffs rather than the class action 15:48:42
4 lawyers, once you include the real life Plaintiffs, then 15:48:45
5 the individual issues are brought into even sharper relief, 15:48:48
6 and it's even clearer that they predominated. 15:48:52

7 So what we have for these individual Plaintiffs 15:48:56

8 is we have some fact sheets that they filled out, and in 15:48:59
9 some instances we have some depositions. So, I want to go 15:49:03
10 through and spend a minute or two on each one of the people 15:49:07
11 that the class action lawyers say are representatives of 15:49:09
12 the classes that they want to certify. Oops, I'm going to 15:49:12
13 fast. 15:49:17
14 Joseph D'Agui, I think is how his name is 15:49:19
15 pronounced, he's a representative of the personal injury 15:49:23
16 class. He's 83 years old and lives in New Jersey. He took 15:49:28
17 .4 relatively late in the game. Started in February of 15:49:33
18 2001. Stopped when the medicine was withdrawn from the 15:49:37
19 market. Now, here's a category you're going to see on all 15:49:43
20 of them. Other drugs while on Baycol. These are important 15:49:48
21 because other drugs can also have some of the same side 15:49:52
22 affects that Baycol can have, and anybody could find that 15:50:03
23 out by looking them up in the Physician's Desk Reference. 15:50:03
24 So, there's a whole bunch of drugs that he took 15:50:05
25 while taking Baycol, I can't pronounce most of them, and 15:50:08

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1 statins that he took after Baycol. He took Zocor after he 15:50:13
2 took Baycol. This is also potentially significant, Your 15:50:17
3 Honor, if, for example, we were talking about aches and 15:50:23
4 pains which he now may say he is experiencing. And he 15:50:25
5 maybe attributing it back to when he took Baycol in August 15:50:31
6 of 2001. But then aches and pains also show up as a side 15:50:36
7 effect of Zocor which he's taking here in 2003. And it 15:50:42

8 also is relevant when we talk about medical monitoring. 15:50:48

9 There's a couple of tests that their expert says 15:50:52

10 comprise the medical monitoring program. One of them is a 15:50:57

11 blood pressure test. One of them is a creatinine-level 15:51:02

12 test. Well, you could have heightened creatinine for a 15:51:09

13 whole bunch of reasons, including that you took Baycol or 15:51:15

14 that you took Zocor. So, if you had medical monitoring 15:51:19

15 here in 2003 of somebody who stopped taking Baycol in 2001 15:51:23

16 and has been taking Zocor ever since, you know, there is a 15:51:31

17 real question of what is it you are monitoring. If you're 15:51:35

18 looking at his creatinine levels, what does it tell you? 15:51:40

19 Where do those come from? 15:51:43

20 Now, Mr. D'Agui's alleged injuries, he includes 15:51:47

21 Rhabdo, leg pain, and here's where we start to get into 15:51:55

22 some issues that actually are pretty important when you 15:51:59

23 talk about whether or not we're going to have a mass trial 15:52:02

24 on injuries and whether the individuals in the class are 15:52:09

25 then going to be bound by the outcome and collaterally 15:52:13

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1 estopped when they go back for their individuals trials. 15:52:18

2 He also claims constipation and psychological injuries, 15:52:21

3 including sleep disruption. 15:52:27

4 Medical history. This is important for every 15:52:31

5 single plaintiff in the class because some of the 15:52:35

6 conditions that are -- can be caused by Baycol, I already 15:52:37

7 mentioned they can also be caused by other medications and 15:52:43

8 they can be caused by medical conditions. So -- and a lot 15:52:49
9 of these plaintiffs have serious medical histories because 15:52:54
10 they were sick people who had a lot of things wrong with 15:52:58
11 them. That's one of the reasons why they were taking 15:53:01
12 Baycol in the first place. 15:53:04

13 Here we have diabetes, spinal stenosis, leg 15:53:07
14 weakness. You know, this kind of thing when we talk about 15:53:12
15 individual injuries, inquiries are going to be important 15:53:19
16 when get to causation. You know, you can have a general 15:53:21
17 verdict that says Baycol can cause leg pains. And let's 15:53:25
18 say they win that one, and we go to trial with D'Agui and 15:53:33
19 he says I've got leg pains, and we take him at his word, 15:53:36
20 and we say, you know, that's because you had this spinal 15:53:40
21 stenosis with leg weakness, and it's not because of Baycol. 15:53:44

22 Similarly, he's got hypertension, prostate 15:53:49
23 cancer, heart palpitations, insomnia. These are conditions 15:53:53
24 that existed before he took Baycol. So, when he goes on to 15:54:00
25 his trial and says that Baycol has disrupted my sleep, 15:54:07

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1 we'll say maybe it has something to do with the fact that 15:54:10
2 you've had insomnia for a long time. 15:54:15

3 Then on the post-Baycol testing, I mention, 15:54:17
4 Judge, that the expert hired by the class action lawyers 15:54:20
5 says that the medical monitoring that he's proposing should 15:54:24
6 consist of a single visit where you get your blood pressure 15:54:29
7 taken and your creatinine level tested. That's the 15:54:33

8 monitoring program -- one visit, blood pressure taken, 15:54:38
9 creatinine measured. 15:54:44
10 Now, this fellow, now he's from the personal 15:54:47
11 injury class, but he's already got his blood pressure 15:54:51
12 taken, and he already got his creatinine levels tested, and 15:54:54
13 he got those taken and tested for reasons having nothing to 15:54:59
14 do with Baycol because he had diabetes, and these are 15:55:04
15 standard things when you have diabetes. And you get your 15:55:09
16 blood pressure -- every time you walk into the doctor's 15:55:15
17 office you get your blood pressure tested, especially if 15:55:16
18 you have hypertension, which is high blood pressure. 15:55:20
19 And, so, when we look at the legal elements for 15:55:25
20 making out a medical monitoring claim, one of them is the 15:55:26
21 people are not already getting the same tests as part of 15:55:34
22 their routine medical care. So, here we see the very first 15:55:38
23 person is already getting the routine tests as part of his 15:55:43
24 normal medical care. So, that's just a snapshots of Mr. 15:55:46
25 D'Agui. 15:55:55

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1 Here's Mr. Sample, and I must say that if you're 15:55:55
2 going to have a class rep, a name like Sample is good. I 15:55:59
3 was looking for Francis Typical or something like that, but 15:56:05
4 we have Edward Sample, personal injury class, 72, law of 15:56:08
5 Arkansas where we saw that there were some peculiarities 15:56:15
6 there. These are the kinds of facts that are going to 15:56:19
7 complicate cases. He took the .03 milligram in December of 15:56:22

8 '99, but his doctor on December 16th told him to stop 15:56:28
9 taking them. It's unclear whether he did stopped taking it 15:56:32
10 before January 20th when he was diagnosed with Rhabdo. So, 15:56:39
11 there's this gap in time. We don't know what happened. 15:56:43
12 Other drugs while he was on Baycol. One of them 15:56:46
13 that he took was Gemfibrozil. This was at a time when we 15:56:54
14 were telling people don't take Baycol when you're taking 15:56:58
15 Gemfibrozil. But he was taking Baycol when he was taking 15:57:00
16 Gemfibrozil. And his doctor was prescribing them. Maybe 15:57:07
17 his doctor had a good reason for it, but there was a 15:57:12
18 warning that said the possibility of Rhabdo increases if 15:57:15
19 you takes Baycol with Gemfibrozil, so watch out. 15:57:18
20 Now, the Plaintiffs will come back and they's 15:57:24
21 say, yeah, but the warning you had then wasn't as good as 15:57:27
22 the warning you had later. And they may have a point, but 15:57:29
23 all that does is underscore how each one of these cases is 15:57:32
24 going to turn on the individual facts, the intersection of 15:57:35
25 all of those facts about what we did when with intersecting 15:57:41

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1 with the individual stories of the Plaintiffs who took a 15:57:44
2 bunch of other medicines. 15:57:48
3 Statins, after Baycol, he took Pravachol and kept 15:57:51
4 taking with Gemfibrozil. And Gemfibrozil, generally, is 15:57:56
5 not taken with any statin, but his doctor obviously felt 15:58:00
6 that his condition was such that even though there are 15:58:05
7 heightened risks of taking a statin with Gemfibrozil, given 15:58:08

8 his medical condition, the potential benefits of that drug 15:58:15
9 combination outweighed the risks. That's what doctors are 15:58:20
10 supposed to do for a living. 15:58:23

11 And I have to explain to the jury in Mr. Samples' 15:58:24
12 case the fact that somebody takes that combination of drugs 15:58:29
13 because they've got a serious condition that can't be 15:58:32
14 treated in some other way and ends up experiencing one of 15:58:37
15 the side effects that's warned about in the label doesn't 15:58:41
16 mean anybody did anything wrong. This is going to be a 15:58:45
17 highly individual case. 15:58:47

18 Alleged injuries, Rhabdo, renal insufficiency, 15:58:49
19 muscle pain, loss of strength, he's got a medical history 15:58:53
20 like so many do, heart disease, three heart attacks, bypass 15:58:58
21 surgery, diabetes, hypothyroidism, etc., depression, 15:59:03
22 arthritis. Maybe that contributes to the muscle pains. 15:59:08

23 Once again, he has gotten the two tests that 15:59:14
24 their expert says would comprise a medical monitoring 15:59:17
25 program, and he got them for reasons having nothing to do 15:59:23

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1 with taking Baycol. He got them because of his other 15:59:25
2 conditions. And in that sense, he truly is typical of the 15:59:29
3 class. 15:59:33

4 Katherine Swearengin, 81 years old from Colorado. 15:59:40
5 I'm trying to remember whether Ms. Swearengin was the very 15:59:48
6 thin person or the very heavy person. She was the thin -- 15:59:53
7 we are going to have the heavy person later, but Ms. 15:59:59
8 Swearengin was thin, and, so, she was taking 8 milligrams 16:00:04

9 from October, 2000 for 29 days. So, she was in that 16:00:08
10 category -- 19 days. She's in that category where at some 16:00:18
11 point and time a warning specifically identified old, thin 16:00:28
12 ladies as people who are particularly susceptible. As I 16:00:28
13 sit here right now, I can't remember whether those warnings 16:00:32
14 were out before or after she was taking her medicine. 16:00:35
15 That's going to be important to her case. 16:00:39
16 But for today's purpose, what it illustrates is 16:00:41
17 how individual these cases are going to be, because if the 16:00:44
18 warnings were out before she took it, we are going to say, 16:00:50
19 gee whiz, we told her doctor you have to especially careful 16:00:51
20 with old, thin ladies, of if we didn't have it out in time, 16:00:58
21 they are going to say, they should have told her doctor to 16:01:03
22 be especially careful about old, thin ladies. What took 16:01:05
23 them so long. And we are going to be asking questions 16:01:09
24 about why she started on .8 because from day one we said 16:01:14
25 don't start on .8, start on .4. All of those are going to 16:01:17

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1 be individual facts. She took a bunch of different kinds 16:01:22
2 of medicine while she was on Baycol. Her alleged injuries, 16:01:24
3 Rhabdo, muscle weakness, pain, fatigue, dizziness. Medical 16:01:29
4 history, coronary artery disease, degenerative arthritis, 16:01:36
5 bilateral knee replacement, osteoporosis, heart attacks. 16:01:43
6 She's had bilateral knee replacement and osteoporosis, 16:01:47
7 degenerative arthritis. We're going to point to these 16:01:52
8 things when she says muscle weakness and pain must be due 16:01:54

9 to Baycol rather than pre-existing medical conditions. And 16:01:57
10 once again, she's already gotten the two tests that their 16:02:02
11 doctor says people should get, and she got it for reasons 16:02:06
12 having nothing to do with Baycol. 16:02:09
13 Now on these two people, what we got here are -- 16:02:12
14 the two people I just went through. Mr. Sample, remember, 16:02:18
15 he took Gemfibrozil along with Baycol. And Ms. Swearingin, 16:02:20
16 she started at .8. Now, we told people don't start at .8. 16:02:28
17 And we told people don't take Baycol along with 16:02:33
18 Gemfibrozil. 16:02:37
19 So, in these two cases, two of the class reps for 16:02:38
20 personal injury cases, there are going to be some serious 16:02:43
21 questions about comparative fault. As I said, maybe the 16:02:47
22 doctors had great reasons for doing this, but maybe they 16:02:50
23 were asleep at the switch. And maybe the jury is going to 16:02:55
24 decide that it's the doctors fault, or some of the blame 16:02:59
25 belongs on the doctor. Or maybe we'll find out that the 16:03:02

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1 doctor warned them and warned of the risk, but they said, 16:03:06
2 no, I still want to take it, so, the jury might say, you 16:03:10
3 bear some of the responsibility for the decision because 16:03:16
4 you really did have your eyes opened. So, we have serious 16:03:17
5 comparative fault, I hesitate to use the word fault, 16:03:22
6 comparative responsibility issues here with these two 16:03:28
7 plaintiffs, and what the cases have said, the Rink case has 16:03:30
8 said, and I'm quoting here, that when you've got the 16:03:35

9 existence of issues of comparative fault, it, "practically 16:03:38
10 guarantees a Seventh Amendment violation." And that would 16:03:47
11 be if you had a class trial on general causation or general 16:03:47
12 liability that focused only on us. You'd have one jury 16:03:54
13 deciding that. And then we got another jury deciding 16:03:59
14 comparative fault issues. And that jury would be looking 16:04:02
15 at the same evidence and making the same determination as 16:04:07
16 to whether we did something wrong. 16:04:09
17 So, when you've got comparative fault issues 16:04:12
18 lurking out there, it guarantees a Seventh Amendment 16:04:16
19 violation. And the District Court here in Minnesota in the 16:04:18
20 Christian case has said that the mere spectator of a Seventh 16:04:23
21 Amendment violation -- excuse me, the mere spectator of a 16:04:29
22 Seventh Amendment violation should lead a court not to 16:04:32
23 bifurcate under Rule 42, which, of course, is one of the 16:04:35
24 procedures that they have as advanced as an alternative to 16:04:40
25 certification. So that the Seventh Amendment issues 16:04:46

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1 involved with comparative fault, knock out the class and 16:04:47
2 knock out bifurcation. And the Rome Polank case from the 16:04:51
3 Seventh Circuit is to the same effect. 16:04:59
4 Okay, let's move through. Here's Ms. Gupta. We 16:05:04
5 listed her. She was originally listed as a personal injury 16:05:17
6 class member, therefore, we got the fact sheet and took a 16:05:23
7 deposition and I think on the day before the deposition 16:05:26
8 they withdrew her as a class rep, but she's, of course, a 16:05:28

9 member of the class and may, in fact, be quite typical. 16:05:33
10 She's 54 years old, North Carolina. She took .4, other 16:05:38
11 drugs. You can see she took a lot of different types of 16:05:44
12 medicine. After Baycol, she took Lipitor. So, again, we 16:05:47
13 are going to have questions about whether if she gets 16:05:52
14 tested and there's heightened levels of creatinine and what 16:05:56
15 was that from. 16:06:00

16 Incidentally, Judge, their expert testified under 16:06:02
17 oath that if you take a measure of creatinine three years 16:06:06
18 after somebody stopped taking Baycol and you see a 16:06:10
19 heightened level of creatinine, you cannot draw any 16:06:15
20 conclusion whatsoever whether that heightened level of 16:06:20
21 creatinine was due to taking Baycol. Can't draw any 16:06:24
22 conclusion on that. Especially you can't draw conclusions 16:06:28
23 on it when, in the mean time, she has been taking other 16:06:31
24 medicine that can elevate your creatinine level. 16:06:35

25 She had an extensive medical history. Remember 16:06:42

1 now, she's in the class, anyway, as a personal injury 16:06:44
2 plaintiff. And if you have a general causation trial that 16:06:50
3 she's not going to participate anymore because they decided 16:06:55
4 to use somebody else, she is still going to have a trial 16:07:01
5 down the road on muscle pain all over her body and a sharp 16:07:07
6 pain in her lower stomach. She is going to go back under 16:07:10
7 the Plaintiffs view of the world with a verdict in her 16:07:14
8 pocket that Baycol can cause X, whatever it is. Let's say 16:07:18

9 they have a question about whether Baycol can cause muscle 16:07:28
10 pain all over somebody's body, and the jury says, yes, it 16:07:28
11 can sometimes, depends on the person. Or even a special 16:07:33
12 verdict on whether it can cause sharp pain in the lower 16:07:34
13 stomach. Maybe. 16:07:39
14 So, we got a maybe verdict that we take back to 16:07:41
15 North Carolina and then try the real case and we put in 16:07:44
16 evidence of her medical history, soft tissue rheumatism, I 16:07:46
17 can't pronounce, psychogenic rheumatism, neurogenic 16:07:56
18 myopathy, chronic pain syndrome. Here we've got somebody 16:07:59
19 with chronic pain syndrome complaining about pain, saying 16:08:02
20 it's our fault, myofascial pain, osteoporosis, recurring 16:08:05
21 bursitis, degenerative disease of the cervical spine, heart 16:08:10
22 disease, three heart attacks, bypass surgery, diabetes, 16:08:17
23 hypothyroidism, et cetera. And, of course, she's had tests 16:08:20
24 already because of these other conditions that the medical 16:08:25
25 monitoring experts says she needs because of Baycol. 16:08:29

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1 Now, we are into the medical monitoring class 16:08:41
2 itself. These, now, remember -- you know, in fairness to 16:08:41
3 the Plaintiffs' lawyers, Judge, I've been pointing out that 16:08:43
4 as to these four red people, the ones who are personal 16:08:48
5 injury class members, that they already got these tests 16:08:53
6 that the experts say should be given for medical 16:08:58
7 monitoring. That they already got the blood pressure test 16:09:01
8 and they already got the creatinine level test independent 16:09:05

9 of any concern of that any doctors have with Baycol. And a 16:09:11
10 fair response to me is, well, be sure they were personal 16:09:15
11 injury reps, and maybe that's why they got the test, and 16:09:18
12 they are not representatives of the medical monitoring 16:09:22
13 class. And, in fact, the way that Mr. Chesley defined the 16:09:25
14 medical monitoring class is people who are asymptomatic. 16:09:29
15 There's nothing wrong with them because of Baycol, at least 16:09:35
16 nothing that we know of yet, although we are worried that 16:09:39
17 something might be wrong with them. Therefore, we need 16:09:41
18 these tests. 16:09:45

19 So, let's take a look at the histories of the 16:09:47
20 class representatives they were able to find for the 16:09:50
21 medical monitoring tests. Tina Coutain from my state, 16:09:54
22 Illinois, 43 years old. She took .3 milligrams, '98 16:09:59
23 through '01. She took it for quite some time. She had 16:10:07
24 some other medicines that she took. Alleged injuries -- 16:10:11
25 muscle pain, weakness and fatigue. I just want to stop 16:10:18

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1 here. 16:10:22
2 The class that the class action lawyers say she's 16:10:23
3 representatives of is defined as people who have not yet 16:10:26
4 suffered any injuries because of Baycol who are 16:10:30
5 asymptomatic. But when she says what her story is when she 16:10:37
6 fills out her form and when gives her testimony, she says, 16:10:42
7 I've been injured, muscle pain, back pain -- wrong line. 16:10:44
8 Here we are, muscle pain, weakness, fatigue. So no matter 16:10:51
9 what the class action lawyers say about the class that she 16:11:02

10 represents, she's claiming injuries. And when we go back 16:11:02
11 to Illinois, and I might get to try this one if it's in 16:11:06
12 Illinois, she's going to be asking for money for these 16:11:09
13 injuries even though they say she is representative of the 16:11:10
14 class of people who weren't hurt. Here she is, she is 16:11:13
15 supposed to be the representative of a class of people who 16:11:17
16 are asymptomatic but might have problems and, therefore, 16:11:25
17 need one-time test of blood pressure and creatinine. Well, 16:11:30
18 she's already had that test after she stopped taking 16:11:33
19 Baycol, and she had that test for reasons having nothing to 16:11:38
20 do with Baycol. 16:11:42

21 So, our first class rep is not in the class, and 16:11:45
22 has already gotten the testing that they say the class 16:11:50
23 members haven't gotten but should get. 16:11:51

24 And then we have a little testimony because what 16:12:02
25 we have is a paid expert who's come up with this medical 16:12:02

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1 monitoring program. I'm going to have more to say about 16:12:07
2 him later, but we also have doctors who treat patients for 16:12:11
3 a living. 16:12:14

4 Question: Did any doctor recommend to you that 16:12:17
5 you pursue any medical follow up as a result of your use of 16:12:17
6 Baycol? Could you repeat it? 16:12:22

7 The witness: No. 16:12:25

8 So, that's the first of the medical monitoring 16:12:29
9 representatives. 16:12:31

10 The next one, Pearl Dardar and she's from 16:12:32
11 Louisiana. This is an interesting one because they picked 16:12:38
12 her as a representative for the medical monitoring class, 16:12:41
13 and she lives in the state where the state legislature has 16:12:46
14 enacted a statute that says you can't have medical 16:12:53
15 monitoring unless you also have a present injury. And they 16:12:56
16 have defined the class as people who do not have present 16:13:01
17 injuries. 16:13:05
18 So, their next representative is a woman whose 16:13:08
19 situations such that the state legislature is saying what 16:13:14
20 her claim is about and her class action lawyers saying what 16:13:17
21 her claim is about. She doesn't have a claim. All right. 16:13:23
22 She took .4. She took some other drugs. She's taking 16:13:28
23 Lipitor afterwards. That's important because a lot of the 16:13:33
24 members of the class would have taken other statins, so 16:13:36
25 that if they get their creatinine tested and it's 16:13:39

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1 heightened, we have no idea if it's from Baycol or Lipitor. 16:13:44
2 No matter what the class action lawyers say about her, she 16:13:48
3 says that she was injured. Wheezing which has since been 16:13:53
4 resolved, shortness of breath, cramping. Medical history, 16:13:56
5 she's insulin dependent, diabetes. She was the one who's 16:14:00
6 overweight and not the thin, old lady. That obesity might 16:14:07
7 have something to do with the shortness of breath, but that 16:14:12
8 will have to wait for the individual trial down in Baton 16:14:15
9 Rouge. Hypertension, that probably explains why she's 16:14:21

10 already got the blood pressure tests. Here she is a class 16:14:25
11 member that they say is typical of the people who have not 16:14:28
12 gotten this program but need it. She's gotten in the 16:14:30
13 program for reasons not having to do with Baycol. 16:14:36
14 Her testimony. Did Dr. Johnson recommend that 16:14:38
15 you receive any medical follow up as a result of your use 16:14:40
16 of Baycol? No, she didn't tell. 16:14:45
17 Question: Have you ever seen Dr. Johnson since 16:14:47
18 you went off Baycol? Yes. Have you seen any other 16:14:50
19 physicians since you went off Baycol? No. 16:14:54
20 So her doctor, treating physician, doesn't think 16:14:57
21 she needs these tests that are being imposed on her, but 16:15:00
22 happily for her, she's already had them anyway. So, she is 16:15:03
23 one of their class reps. 16:15:06
24 The next one -- and, of course, each one of these 16:15:08
25 is going to have different story as to liability issue as 16:15:13

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1 to us that they start taking the medicine at different 16:15:18
2 times and different doses. 16:15:20
3 Ms. Swearengin who took .8 had a different story
4 from the next person we'll click on, Jack Hartman, 67. He 16:15:29
5 is from Minnesota, and in Minnesota federal courts have 16:15:33
6 rejected medical monitoring claims. So, he's a class rep 16:15:36
7 and he lives in the state where court says you don't have a 16:15:40
8 cause of action. He took Gemfibrozil after he took Baycol. 16:15:44
9 Gemfibrozil, incidentally, can cause Rhabdo and many of the 16:15:54

10 same conditions that can be caused by statins. 16:15:57
11 They say that he's asymptomatic like all the 16:16:01
12 other class members. He begs to differ. He says that he 16:16:07
13 was injured by Baycol even though they say he was not. 16:16:12
14 He's got a medical history of diabetes, pernicious anemia, 16:16:15
15 prostate problems, etc., degenerative disk disease that can 16:16:20
16 contribute to his weakness, bilateral leg weakness that 16:16:28
17 might explain the leg pain. And, again, like the others, 16:16:34
18 he's already gotten the test because they are routine 16:16:37
19 tests. Blood pressure tests, these are people who have a 16:16:41
20 lot of medical problems and they go to the doctor 16:16:45
21 regularly, and the doctor takes their blood pressure all 16:16:46
22 the time. Because of the nature of the problems that they 16:16:49
23 have, they always get this test, too. 16:16:53
24 His deposition. Again, we were contrasting real 16:16:59
25 life doctors who take care of patients to hired experts who 16:17:05

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1 are designing a medical monitoring protocol. 16:17:09
2 Mr. Hartman, did any doctor recommend that you 16:17:12
3 receive any medical follow up as a result of your use of 16:17:17
4 Baycol? Answer: I don't think so. 16:17:21
5 William Krohn, 69 years old, another Minnesotan. 16:17:28
6 Unfortunately for him, the federal courts have decided that 16:17:34
7 he doesn't have a cause of action for the theory under 16:17:40
8 which they are holding him for as a class representative. 16:17:45
9 He took 3 milligrams from '99 to 2000. His story is going 16:17:50

10 to be a lot different from everybody else. Statins after 16:17:55
11 Baycol. 16:18:04
12 Here's an interesting one. He took Lipitor and 16:18:04
13 then he switched from Lipitor to Mevacor. Why did he 16:18:04
14 switch from Lipitor? Because while he was on Lipitor, he 16:18:08
15 experienced muscle soreness and complaints. Lipitor warns 16:18:10
16 about aches and pains just like we warn about aches and 16:18:14
17 pains. When he took Lipitor and he got aches and pains, he 16:18:20
18 switched to Mevacor. When he took Baycol, he claims to 16:18:23
19 have gotten leg pains. All of a sudden he's a class 16:18:28
20 representative in a 900,000-person lawsuit. 16:18:32
21 Medical history. You can see he's got heart 16:18:37
22 problems. Once again, forgetting about the fact that he 16:18:40
23 doesn't have a cause of action because he lives in 16:18:48
24 Minnesota. He, like the others, routinely gets the medical 16:18:48
25 tests that their expert claims are needed by the class 16:18:53

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1 members. 16:18:59
2 Then, again, contrasting the expert who was hired 16:19:03
3 to come up with the monitoring program, real life doctor. 16:19:07
4 Sir, has any doctor told you needed any monitoring, any 16:19:12
5 testing for your prior use of Baycol? Answer: No. And if 16:19:15
6 we test him again and he's got heightened creatinine is 16:19:22
7 that Baycol, is that Lipitor, is it Mevacor? 16:19:26
8 Marsha Miller. If we just back up for a minute, 16:19:33
9 we see that Marsha Miller, she is one of the people who 16:19:36

10 took two different doses, so when it gets to her individual 16:19:41
11 liability claims, hers is going to be different from a lot 16:19:46
12 of others because she's going to be talking about what was 16:19:48
13 known when .3 was around and what was know when .4 was 16:19:51
14 around, and should we have come out with .4, and should we 16:19:55
15 have done something different. So, we're going to have 16:19:59
16 those kinds of individual facts. 16:20:02

17 And then when we get to her situation, she's 60 16:20:03
18 years old from Ohio. She's taken a lot of other medicines. 16:20:06
19 She is taken Lipitor after Baycol. So, we're going to have 16:20:12
20 that same question with creatinine, alleged injuries. Once 16:20:18
21 again, Judge, every single person that they have put forth 16:20:23
22 as class rep for the medical monitoring class, people who 16:20:25
23 are asymptomatic who have suffered no injuries as of yet, 16:20:32
24 every single one of them disagrees with the class action 16:20:32
25 lawyers and claims that they suffered injuries. 16:20:36

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1 In Marsha Miller's case, ache and pains, fatigue, 16:20:38
2 urinary tract infection. She alleges that and all symptoms 16:20:43
3 have resolved except for the right arm and shoulder pain. 16:20:50
4 And all of this, according to her, is because of Baycol.
5 We looked at her medical history, musculoskeletal 16:20:54
6 complaints. That might have something to do with the aches 16:20:58
7 and pains when they get down to the individual case, torn 16:21:01
8 tendon in the shoulders. She says that she's got shoulder 16:21:05
9 pain because of Baycol. That might be because of a torn

10 tendon. Acute neck and right shoulder sprain. Once again, 16:21:09
11 the thing that she blames on Baycol. We're going to point 16:21:14
12 to some other potential causes. And I'm spending a lot of 16:21:21
13 time on this, but, it's her case that's going to be 16:21:23
14 advanced by a general verdict that says Baycol can cause 16:21:26
15 aches and pains. She's going to say -- go back to 16:21:31
16 Columbus, Ohio and I've got a verdict in my pocket that 16:21:37
17 Baycol caused aches and pains. And then the real trial 16:21:41
18 begins, and the individual issues are going to predominate. 16:21:45
19 Like the others, for reasons having nothing to do 16:21:54
20 with Baycol, she's already got the blood pressure tests. 16:21:55
21 She's already got the creatinine test. Like the others, 16:22:00
22 her real life doctor doesn't see a need for any of this 16:22:05
23 medical follow up that the class action lawyers would like 16:22:08
24 us to fund and then pay them for securing. 16:22:11
25 Now, we move to the refund class. Joan 16:22:23

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1 Dobrowits, 66, from Illinois, .4. She took Baycol pretty 16:22:30
2 late in the game, last couple of months it was on the 16:22:39
3 market. She had some other medicines. She is taking 16:22:41
4 Lipitor. Since then she's hypertension and obesity. She 16:22:44
5 is not -- she's in the refund class. I don't know whether 16:22:50
6 or not, I can't remember off the top of my head whether 16:23:01
7 that's supposed to include people who were injured or not. 16:23:01
8 I guess it overlaps. So, anyway, she claimed that she was 16:23:07
9 injured, hypertension and obesity. She's already had the 16:23:09

10 tests that they say everybody should have. 16:23:13
11 She gave some interesting testimony. It's 16:23:17
12 interesting because they hold her out as a representative 16:23:23
13 of the refund class. Ma'am, do you feel cheated by what 16:23:25
14 you paid for Baycol? Answer: I don't feel cheated for 16:23:28
15 what I paid. Question -- and I need to give you a little 16:23:33
16 background. She had two prescriptions that cost \$45 a 16:23:37
17 piece. One prescription she took the medicine. The other 16:23:42
18 prescription she got in August, and as soon as the 16:23:47
19 withdrawal was announced, she stopped take Baycol. So she 16:23:50
20 never took that prescription. Since she had a \$45 16:23:55
21 prescription that she paid for and she never took the 16:24:00
22 medicine. 16:24:03
23 One of the things we did when we withdrew Baycol 16:24:04
24 from the market, because we said listen, if anybody is out 16:24:10
25 there who purchased Baycol, obviously, you're going to have 16:24:14

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1 second thoughts about taking Baycol. We don't want you to. 16:24:16
2 You give us back your Baycol, and we'll give you a full 16:24:21
3 refund for what you pay. 16:24:25
4 So, and you were given the opportunity to get the 16:24:26
5 \$45 for the second prescription by Bayer, correct? Answer: 16:24:32
6 That's correct. And you had chose not to do that at that 16:24:39
7 time? Answer: That's correct. By the advice of your of 16:24:41
8 your lawyer friends, correct? Answer: Correct. 16:24:47
9 She's a class rep and half of her claim we wanted 16:24:51

10 to give her the money back and she wouldn't take it because 16:24:57
11 the lawyer told her that maybe -- we don't know what the 16:25:00
12 lawyer told her, but on advice of counsel. 16:25:03
13 Last person is James Broadway, another member of 16:25:08
14 the refund class, 68, from Louisiana, taking Lipitor since 16:25:12
15 he came off of Baycol. Like every single person that we've 16:25:17
16 seen, he claims injury from Baycol. I don't know if they 16:25:25
17 want to have a general verdict form or general causation 16:25:32
18 verdict on whether Baycol can cause heart skip, but at 16:25:36
19 least we have to think about that because it's not going to 16:25:41
20 do any good if you don't include it. Weakness and pain in 16:25:43
21 hips and leg. Then he's got a medical history that might 16:25:50
22 explain some of this. Like everybody else that we've 16:25:54
23 looked at, every single class representative of every 16:25:56
24 single class, he, for reasons having nothing to do with 16:26:02
25 Baycol, has already received the tests that their hired 16:26:04

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1 expert says is needed for medical monitoring. 16:26:08
2 And then the testimony. We heard that Baycol 16:26:11
3 doesn't work. It's not effective. And one reason that 16:26:15
4 everybody should get a refund is because the medicine 16:26:20
5 doesn't work, even if they are one of the lucky ones, as 16:26:23
6 one of the lawyers said, as I would say, one of the lucky 16:26:28
7 99 percent whom the medicine worked perfectly. They said, 16:26:31
8 you know, they weren't injured. She said nevertheless the 16:26:37
9 medicine didn't work, so they're entitled to a refund, and 16:26:40

10 the medicine doesn't work. It didn't do what it said it 16:26:45
11 was going to do, lower the cholesterol. Well, he said that 16:26:49
12 it did lower his cholesterol. So, he wants a refund for 16:26:55
13 medicine that did what it was supposed to do. And then we 16:26:55
14 are going to have a question of whether -- even though the 16:26:59
15 medicine did what it was supposed to do, which was lower 16:27:05
16 his cholesterol, whether he's entitled to a refund or 16:27:08
17 damages for personal injury because he says a heart skip 16:27:15
18 was caused by Baycol. And when we get to that one, we're 16:27:19
19 going to say, you know what, maybe that was because of your 16:27:22
20 abnormal heart rhythm because your pre-existing abnormal 16:27:24
21 heart rhythm is fancy way of saying heart skip. 16:27:30
22 So, those are the individual representatives of 16:27:36
23 the classes. And if I got -- if my tone turned dark, it's 16:27:40
24 not because these individuals have done anything wrong, 16:27:49
25 Your Honor. And it's not because of any ill-feelings that 16:27:54

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1 we have towards them. It's because they have been ill-used 16:28:02
2 in this litigation when they have been held out as 16:28:05
3 representatives of classes that they don't even belong in. 16:28:08
4 Now, while which are talking -- 16:28:13
5 THE COURT: Before -- this is just on the side 16:28:25
6 dealing with the personal injury cases, if you could pull 16:28:25
7 one of those up for me. 16:28:30
8 MR. BECK: Sure. Any one in particular? 16:28:32
9 THE COURT: It doesn't matter. 16:28:38

10 MR. BECK: Gupta was a former one, so I'll take 16:28:38
11 the first one A'gui. 16:28:39
12 THE COURT: Dealing with the types of cases that 16:28:46
13 you are settling, and those are the serious Rhabdo cases. 16:28:47
14 MR. BECK: Rhabdo we define as serious for 16:29:01
15 settlement purposes. We're settling Rhabdo cases. 16:29:04
16 THE COURT: Rhabdo cases, are those the cases 16:29:06
17 where those individuals don't have any other problems or 16:29:11
18 are they -- is this typical? 16:29:18
19 MR. BECK: This is typical. We've got, you know, 16:29:22
20 everybody -- not everybody -- almost everybody -- 16:29:26
21 THE COURT: You see what I'm getting at? These 16:29:28
22 are elderly people that have a lot of problems. 16:29:31
23 MR. BECK: Absolutely. And we are not going to 16:29:37
24 refuse to settle with somebody because -- 16:29:38
25 THE COURT: If I asked the group here how many 16:29:42

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1 are taking a cholesterol-lowered drug, I think we could get 16:29:47
2 a nice sampling. So, I'd like to get in my mind what kind 16:29:54
3 of cases are you settling. This person has a Rhabdo case. 16:29:59
4 If she came -- if he came to you, would he fit under your 16:30:05
5 criteria for settling. 16:30:09
6 MR. BECK: What I propose to do is to take two 16:30:11
7 minutes and click on each one of these and answer that, 16:30:14
8 give you a yes or not. Somebody who knows more about 16:30:17
9 settlement can tell me if I got it wrong. 16:30:20

10 class. She comes in and her lawyer says she's got muscle 16:32:08
11 pain all over her body. She's got sharp pain in her lower 16:32:10
12 stomach, and she'd like some money from you because she 16:32:15
13 took the Baycol. And we say, tell Ms. Gupta we'll see her 16:32:16
14 in court because we are not settling aches and pains case, 16:32:21
15 and we think that these aches and pains are due to all of 16:32:23
16 her other conditions and we are not going to pay that kind 16:32:27
17 of tribute. 16:32:30

18 THE COURT: The rest of them I don't think have 16:32:35
19 Rhabdo. 16:32:38

20 MR. BECK: I don't think they do either

21 THE COURT: No, just so I have a frame of 16:32:38
22 reference. 16:32:40

23 MR. BECK: That's the basic approach we would 16:32:43
24 take. 16:32:45

25 THE COURT: I was just making sure that the 16:32:46

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1 people that you are settling with were pristine clean and 16:32:47
2 only taking Baycol and that was the only thing they were 16:32:53
3 taking. 16:32:57

4 MR. BECK: No, no. They could take a cocktail of 16:33:00
5 medications, any one of which could cause Baycol. They 16:33:00
6 could take them with Gemfib. They could have taken with 16:33:06
7 .8. They could have fallen down the stairs, but if they 16:33:11
8 have Rhabdo that's temporally associated with taking our 16:33:14
9 drug -- our whole point is we don't want to fight in those 16:33:18

10 cases. If somebody has an injury that fairly could be 16:33:22

11 said --

12 THE COURT: I didn't want to obstruct you. I 16:33:23

13 just wanted to --

14 MR. BECK: I get carried away when I start 16:33:28

15 talking the settlement program. I apologize. I don't have 16:33:31

16 quite the same positive passion when I talk about refund 16:33:34

17 class, however, which is what I would like to turn to now. 16:33:39

18 We were talking about refund Plaintiffs, the 16:33:43

19 green guide down here at the bottom. And I showed you the 16:33:44

20 testimony from Mr. Broadway who said that when he took 16:33:49

21 Baycol, his cholesterol went down. We also know that he 16:33:54

22 didn't get Rhabdo. He may claim whatever it is he's going 16:33:59

23 to claim about other ailments, but his cholesterol went 16:34:05

24 down, and he didn't get Rhabdo, and in our view, the 16:34:09

25 medicine worked for him, and they hold him out as someone 16:34:14

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1 who is typical of those who should get refunds for what 16:34:18

2 they paid. 16:34:21

3 When I was listening to the economic analysis, I 16:34:24

4 was wondering how it would work in its full glory because 16:34:27

5 if he wasn't taking Baycol when he had this cholesterol 16:34:32

6 problem, he probably would have been taking Lipitor or some 16:34:37

7 other statin to lower his cholesterol. And let's hope and 16:34:42

8 assume that Lipitor worked for him. Let me put him up and 16:34:47

9 see if he took anything else so I can stop my guessing. 16:34:53

10 Lipitor, there we go. Let's say that he hadn't taken 16:34:58
11 Baycol because we never it put on the market, and instead, 16:35:02
12 during that period from October or November of '99 to 16:35:06
13 August of '01 he was taking Lipitor. And let's say that 16:35:11
14 Lipitor worked just as well as Baycol did and his 16:35:15
15 cholesterol was lowered. And let's say that Lipitor, like 16:35:20
16 Baycol, did not cause Rhabdo or any side effects. Well, 16:35:25
17 his economic condition would be as follows. His 16:35:29
18 medical/economic condition would be as follows. He'd have 16:35:42
19 low cholesterol because the medicine worked, but he would 16:35:42
20 be worse off economically because Lipitor is more expensive 16:35:47
21 than Baycol. 16:35:54
22 So, if we're going to do this kind of -- I just 16:35:55
23 say that to illustrate what I think is, frankly, the 16:35:55
24 silliness of trying to impose this kind of economic damages 16:35:59
25 class. These are not people who got ripped off when they 16:36:03

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1 bought a BMW. These are people who were getting prescribed 16:36:10
2 medicine to lower their cholesterol and the medicine did 16:36:16
3 lower their cholesterol. And if they did not have our 16:36:21
4 medicine, they would have been taken somebody else medicine 16:36:28
5 and maybe it would have lowered their cholesterol, too, but 16:36:31
6 they would have had to pay for it, and they would have paid 16:36:37
7 more money for the other medicine. So nobody suffered any 16:36:38
8 economic damages here. Maybe that goes to the merits of 16:36:43
9 the claim, but since we heard an impassioned plea 16:36:46

10 concerning the cry for justice for this class, I think it's 16:36:51
11 worth pausing and reflecting that in real life, there are 16:36:55
12 no economic damages here. The only way there's damages is 16:36:59
13 if the medicine didn't worked and you got hurt, in which 16:37:04
14 case he's in the personal injury class. 16:37:09
15 Okay, so off we go. There is Mr. Broadway. 16:37:17
16 Lucky for him the medicine worked. And they may say Mr. 16:37:21
17 Broadway is the exception that proves the rule. If he is, 16:37:25
18 then I don't on know why they got him as the class rep, but 16:37:28
19 nevertheless, their class rep the medicine worked. 16:37:34
20 Let's see what his doctor said about whether the 16:37:36
21 medicine worked for other patients, because what we have 16:37:39
22 heard today is testimony from the lawyers who want to 16:37:43
23 represent the classes saying that the medicine was 16:37:49
24 ineffective. The lawyers' testimony, however, differs 16:37:52
25 substantially from the real testimony of the doctors who 16:37:59

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1 prescribed the medicine. Here is his doctor, Dr. Murtor, I 16:38:03
2 think is how his doctor's name is pronounced. Out of the 16:38:10
3 hundreds of patient that you prescribed Baycol to, for how 16:38:14
4 many did Baycol reduce cholesterol? Answer: Practically 16:38:20
5 all of them unless I had to get into higher doses. 16:38:27
6 Question: Of the hundreds of patients that you prescribed 16:38:32
7 Baycol to, did any develop Rhabdo? Answer: No. 16:38:35
8 Let me also move up to Page 94 of his testimony, 16:38:42
9 and I'm actually going to basically take a minute and read 16:38:47

10 the whole page because it's worth contrasting sometimes 16:38:52
11 what the doctors say with what the lawyers say. 16:38:56
12 How many times patients did you prescribe Baycol 16:39:00
13 to? Answer: Practically -- eventually, almost everybody I 16:39:04
14 had. Question: Why did you prescribe Baycol to everybody 16:39:08
15 you had? Answer: Because it was like a little Lipitor, 16:39:12
16 except for about half the price. And a little Lipitor 16:39:17
17 means it was about as effective as Lipitor, except when you 16:39:23
18 got into the high numbers like 40's and the 80's. And but 16:39:23
19 at the level that we were using Baycol, and I think it was 16:39:29
20 .4 and then we went to .8, that was about equivalent to 16:39:33
21 Lipitor 10 and Lipitor 20. Now, once you got to .8, you 16:39:37
22 couldn't compete with Lipitor 40 and 80 because that was 16:39:42
23 the top of the line, and that's where we are today. That's 16:39:46
24 what we are still using. But Baycol was as effective as 16:39:50
25 Lipitor and it would improve the numbers dramatically, 16:39:55

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1 better than all the others right along with Lipitor. 16:39:59
2 So, of course, his hundreds of patients, every 16:40:06
3 single one of whom benefitted from Baycol because their 16:40:07
4 cholesterol went down. And every single one of whom paid 16:40:12
5 less for their medicine than they would have paid if they 16:40:17
6 had been taking Lipitor. Every single one of his patients 16:40:21
7 are in their refund class, because according to the class
8 action lawyers, they got ripped off. 16:40:26
9 I want to show you now, Judge, what the Rezulin 16:40:32

10 court said about a similar claim for a refund class. This 16:40:35
11 is the Rezulin case, Your Honor, and the court says, "In 16:41:27
12 order to obtain restitution of the purchase price of 16:41:32
13 Rezulin, Plaintiffs and class members would be obliged, at 16:41:34
14 least in many jurisdictions, to prove some kind of harm. 16:41:37
15 In other words, although theories presumably could differ," 16:41:41
16 and, of course, that just gets, you know, the 51 state laws 16:41:45
17 issue, "but, in other words, although theories presumably 16:41:48
18 could differ, they would have to establish that they were 16:41:52
19 injured by detrimental reliance on a fraudulent or 16:41:55
20 misleading statement. That the defendants retention of the 16:41:58
21 price they paid for the drug would be unjust, and that the 16:42:01
22 value of the drug given if its allegedly concealed defects 16:42:05
23 was less than the purchase prices or some other variation 16:42:08
24 that would warrant the transfer of money from the 16:42:12
25 defendants to them. Every one of these theories would 16:42:15

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1 involve issues individual --" where are we here. I've got 16:42:19
2 to move up a little bit. Excuse me -- "every one of these 16:42:28
3 theories would involve issues individual to the particular 16:42:35
4 class member. The New Jersey Consumer Fraud Act upon which 16:42:39
5 plaintiffs rely, for example, affords the right to 16:42:45
6 monetary relief only if there has been an ascertainable 16:42:50
7 loss in consequence of the consumer receiving something 16:42:52
8 other than what he bargained for and losing the benefits of 16:42:56
9 the product which he was led to believe he purchased. 16:43:00

10 Plaintiffs contention that everyone that took Rezulin 16:43:00
11 sustained an ascertainable loss, presumably that Rezulin 16:43:06
12 was worthless, but that is not a defensible position. Even 16:43:08
13 Plaintiffs' experts acknowledge that Rezulin was enormously 16:43:12
14 beneficial to many patients." And go over to the next 16:43:19
15 pages. And, incidentally, their paid expert also 16:43:25
16 acknowledged that. 16:43:28
17 The court goes on, "Those patient presumably got 16:43:31
18 their money's worth and suffered no economic injury. And 16:43:38
19 the question whether an individual class member got his or 16:43:38
20 her money's worth is inherently individual. Indeed, it 16:43:41
21 would involve very much the same questions as would a claim 16:43:43
22 for money damages for personal injury." 16:43:48
23 I've been focusing on the class representatives 16:43:52
24 that were chosen by the class action lawyers to represent 16:43:58
25 the classes. We also look through a whole stack of fact 16:44:00

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1 sheets that were submitted by Plaintiffs -- excuse me, Your 16:44:08
2 Honor. We basically grabbed a handful of them, the first 16:44:16
3 900 or so that they gave us we looked at. And what we 16:44:20
4 found is there is just an amazing variety of injuries that 16:44:26
5 people claim they sustained because of Baycol. Let me see 16:44:36
6 if I can get the right slide up here. Here we are. 16:44:42
7 This is -- we just kind of picked some names at 16:44:46
8 random and looked at the injuries. These are injuries -- 16:44:49
9 these not pre-existing medical conditions. These are 16:44:55

10 injuries that these people when they fill out their claim 16:44:57
11 sheets blame on us, and they say I took Baycol and Baycol 16:45:01
12 caused the following problems, gas pain, constipation, 16:45:10
13 reflux, loss of sex drive, eye focusing problems, decreased 16:45:12
14 urine output -- sounds like my last week -- increased urine 16:45:18
15 output, depressed immune system, fatigue, cataracts, 16:45:25
16 sinusitis, drug help, drug-induced hepatitis, pain, weak 16:45:31
17 thumb joints, hearing voices, memory loss, confusion, 16:45:33
18 anxiety, reddish lesions. 16:45:38
19 Now, no matter what the class action lawyers say 16:45:42
20 about how they want to define their class, these were the 16:45:45
21 injuries that these people are claiming. These are the 16:45:49
22 injuries that class members say they sustained. And if 16:45:52
23 they're going do pursue these claims, we're going to have 16:45:54
24 trials over whether Rhabdo causes loss of sex drive or 16:45:59
25 whether it makes your urine output goes up or down or 16:46:07

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1 leaves it the same. And none of this is going to be 16:46:10
2 advanced one inch by common issue trial on whether Baycol 16:46:13
3 caused Rhabdo. 16:46:20
4 Incidentally, Judge, I wouldn't bother convening 16:46:23
5 a jury to decide the issue of whether Baycol can cause 16:46:27
6 Rhabdo, which is one of the issues they pose. Of course, 16:46:29
7 it can cause Rhabdo. We've been saying that on our labels 16:46:32
8 forever. So, we don't need a verdict on that. The 16:46:36
9 question on injuries is going to be can it cause these 16:46:39

10 other things, and not just can it cause these other things, 16:46:43
11 did it cause these other things to these Plaintiffs. 16:46:47
12 Here's a summary of these slides. This touches 16:46:55
13 on, you were asking about percentages, Your Honor, to some 16:47:00
14 point this is a self-selected group because they are people 16:47:05
15 who filed suit. So, obviously, you are going to get a 16:47:11
16 higher percentage of Baycol users who had Rhabdo among 16:47:15
17 those who filed suit than you will among those who didn't 16:47:21
18 file suit. In fact, you would be pretty surprised if you 16:47:27
19 had anybody who suffered from Rhabdo that's associated with 16:47:29
20 Baycol who hasn't filed suit, or at least hired a lawyer. 16:47:31
21 So, anyway you look at these first 909, 70 are 16:47:38
22 Rhabdo, 3 you could say possible Rhabdo, 34 claim kidney 16:47:45
23 failure, 724 we put in generically the aches and pains 16:47:50
24 category. They were described using various types of 16:47:56
25 language. 38 in the miscellaneous physical ailments like 16:48:00

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1 cataracts, 8 psychological injuries, and 32 of them said 16:48:09
2 they didn't suffer any injury at all. 16:48:15
3 So, when we look at the people who filed claims. 16:48:21
4 What we see is that the overwhelming majority of the 16:48:24
5 so-called injury claims are these aches and pains 16:48:28
6 situations. Now, what's going to be important, in the real 16:48:33
7 life trials is that there is going to be causation issues 16:48:42
8 about why do they have aches and pains. There may be an 16:48:46
9 issue about whether somebody really have aches and pains or 16:48:50

10 whether it's just cashing in on our misfortune. 16:48:54
11 Let's assume that all of them had aches and 16:48:59
12 pains, and the question is where did these aches and pains 16:49:00
13 come from? Did they come from Baycol. And, of course, we 16:49:05
14 warned against aches and pains. We said you saw every one 16:49:07
15 of our warning labels. If you experience aches and pains, 16:49:11
16 consult your doctor. And we did that because aches and 16:49:16
17 pains could be precursor to Rhabdo, an early warning signal 16:49:20
18 from Rhabdo. So, we said if you got any aches and pains, 16:49:24
19 talks to your doctor. Well, there's all these people that 16:49:25
20 got aches and pains, you know, didn't get Rhabdo and they 16:49:31
21 claim their aches and pains are our fault. 16:49:31
22 Well, what's going to happen at the trials, no 16:49:34
23 matter what happens in this court, no matter what happens 16:49:38
24 if they are able to persuade Your Honor to certify a class, 16:49:41
25 we were going to have questions about what really caused 16:49:47

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1 the aches and pains. 16:49:51
2 What we've done here, now, is this is a list -- 16:49:55
3 we went through all the class representatives, the injury 16:49:57
4 class, medical monitoring class, and the refund class, and 16:50:05
5 we listed all of the medical conditions, the medical 16:50:05
6 conditions having nothing to do with Baycol that they had 16:50:09
7 listed on their record. And, now, what we did is we said 16:50:13
8 maybe the aches and pains could come from is these other 16:50:17
9 medical conditions. So, what I'm going to do here -- and 16:50:21

10 this is testimony that's going to have to come in in actual 16:50:25
11 trials. You know, we consulted with a nurse on this, so 16:50:28
12 I'm not going to pretend that this is based on a peer 16:50:33
13 reviewed article. But the nurse practitioner, I said, well 16:50:40
14 circle in red or highlight in red these medical conditions 16:50:41
15 that the class reps had that might account for the aches 16:50:47
16 and pains. 16:50:52
17 So, Your Honor, the injury class here is 16:51:34
18 overwhelmingly aches and pains, and they want you to 16:51:34
19 certify a class and get some kind of a verdict that says 16:51:37
20 Baycol can cause aches and pains and that is not going to 16:51:45
21 advance the ball because they all have a host of medical 16:51:52
22 conditions, all of which can result in aches and pains. 16:51:56
23 And you know what, Judge, a lot of them are old people and 16:51:59
24 old people get aches and pains. 16:52:04
25 THE COURT: I beg your pardon. (Laughter). 16:52:06

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1 MR. BECK: I don't have any color treatment on 16:52:17
2 this one, but -- 16:52:20
3 THE COURT: The reason I said that is because my 16:52:21
4 kids think that I'm old. 16:52:26
5 MR. BECK: Well, I know better, Your Honor. My 16:52:30
6 kids are older than your kids. 16:52:31
7 THE COURT: And when I walk up the stairs and cry 16:52:34
8 out about pain, then I'm an old man. 16:52:38
9 MR. BECK: Well, I hope you didn't take Baycol, 16:52:42

10 because otherwise you would in the class. 16:52:45

11 THE COURT: No, I take Lipitor. (Laughter). 16:52:49

12 MR. BECK: Read the label because it can cause 16:52:51

13 it, too. 16:52:54

14 We also went and took a look at the medications. 16:52:56

15 Remember, we went through all those medications that they 16:53:00

16 all took. So, we listed here by referencing the 16:53:04

17 Physician's Desk Reference. Just looking at the class reps 16:53:07

18 now. All of these medicines that they took, including 16:53:13

19 Lipitor, like you're taking, and all these other medicines 16:53:18

20 that do other things, all of those can cause aches and 16:53:24

21 pains. So, this is going to be obviously overwhelmingly 16:53:33

22 individual questions on causation, and this goes to the 16:53:37

23 overwhelming majority of the claimants here. 16:53:42

24 This also gives you some indication, I hope, Your 16:53:46

25 Honor, of why it is we aren't writing checks to people who 16:53:49

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1 show up and say, I saw a commercial on cable television 16:53:55

2 last night from a law firm where it said if you took Baycol 16:53:59

3 call this new number, you may have a claim. I've got aches 16:54:05

4 and pains. Write me a check. We are saying no to those 16:54:13

5 people. 16:54:15

6 There's even other causes for Rhabdo. Other 16:54:15

7 statins can cause Rhabdo. Gemfibrozil by itself can cause 16:54:21

8 Rhabdo. The single leading cause of Rhabdo in the United 16:54:29

9 States is alcoholism. It's a big problem. This comes from 16:54:33

10 the Annals of Clinical Bio-Chemistry -- trauma, you get in 16:54:36
11 an accident and fall down the stairs. You can have the 16:54:43
12 same -- when I say Rhabdo, I mean not just you were sober 16:54:46
13 and you get the real condition of Rhabdo, that leakage to 16:54:49
14 the muscular walls, crushed injuries, all kinds of things, 16:54:54
15 snake bites, lightning strikes. You know, there's a host 16:54:58
16 of potential causes. 16:55:03
17 This, you know, frankly, is unlikely to be a big 16:55:06
18 issue in any particular cause, certainly in our settlement 16:55:08
19 program. If somebody comes to us and there is a temporal 16:55:11
20 association between Rhabdo and taking Baycol, we are 16:55:21
21 treating that as established causation. But there may be 16:55:21
22 cases where, in effect, I think there are claims that have 16:55:28
23 been filed here where they stopped taking Baycol and they 16:55:30
24 start taking a different statin, or they start taking 16:55:35
25 Gemfibrozil and four months later, they come down with 16:55:38

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1 Rhabdo and they're claiming it's because of us. And then 16:55:42
2 it doesn't make any sense because our drug then has been 16:55:47
3 flushed out of the body. They're taking other drugs that 16:55:53
4 can cause Rhabdo and they're trying to blame us. So, even 16:55:55
5 on Rhabdo in some cases there can be issues. 16:56:00
6 I want -- I've been talking about real life 16:56:10
7 individual causation. I want to spend a few moments now on 16:56:11
8 their arguments concerning general causation because their 16:56:19
9 response is, well, we don't want to try that cause over 16:56:22

10 whether is Ms. Swearengin's problems are really due to 16:56:25
11 Baycol. We just want a general causation verdict about 16:56:30
12 what problems can be caused by Baycol. 16:56:34
13 I mentioned already that at various points in the 16:56:39
14 class action briefing, they have talked about how they want 16:56:44
15 a class action to determine whether Baycol can cause 16:56:48
16 Rhabdo. We don't need a class action to determine whether 16:56:55
17 Baycol can cause Rhabdo. That's admitted. That's on our 16:56:58
18 labels. We agree that Baycol can cause Rhabdo. So, the 16:57:03
19 signal disease or condition that they hold out, there isn't 16:57:10
20 any dispute that it can be caused by Baycol. And, of 16:57:13
21 course, we told people that from the first day we put our 16:57:19
22 medicine on the market. 16:57:24
23 Then we get to the big aches and pains group. 16:57:25
24 And as I said, that is the vast, vast majority of claims, 16:57:28
25 aches and pains. And, then, probably more than Rhabdo, if 16:57:35

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1 you really looked at it, if you got into the class and got 16:57:41
2 out of the people who filed claims already, if you got into 16:57:45
3 the class and did this sort of thing, you will find that 16:57:46
4 Rhabdo would be a pretty tiny percentage and there would 16:57:51
5 probably be a lot more people claiming whacky injuries than 16:57:56
6 claiming Rhabdo. You know, claiming silly, not silly, they 16:57:59
7 are not silly injuries, but it's silly to pretend they came 16:58:03
8 from Baycol. They are the kind of injuries that someone, 16:58:08
9 I'm sure, is going to stand up and say we don't pretend 16:58:11

10 those came from Baycol. We don't pretend that when that 16:58:15
11 lady started to hear voices that that was due to Baycol. 16:58:19
12 And we don't pretend that the loss of sex drive was due to 16:58:25
13 Baycol. But if you took a survey of the class, you have a 16:58:29
14 heck of a lot more people claiming things like that than 16:58:33
15 are going to be claiming Rhabdo. But the vast majority are 16:58:41
16 going to be claiming aches and because everybody has got 16:58:41
17 aches and pains. 16:58:44

18 As I said, Your Honor, in terms of the need for 16:58:46
19 general causation class here, we warned against aches and 16:58:47
20 pains, every statin warns about aches and pains, because as 16:58:52
21 I said, it can be a precursor of Rhabdo. We say go see 16:58:56
22 your doctor if you get aches and pains. We also know, 16:59:03
23 however, that there are hundreds of other causes of aches 16:59:07
24 and pains. The red chart that showed the medical 16:59:09
25 conditions that can cause aches and pains, the other 16:59:13

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1 medications that can cause aches and pains. So, a general 16:59:15
2 verdict that Baycol could cause aches and pains is not 16:59:20
3 going to advance anybody's litigation because the question 16:59:24
4 isn't going to be could Baycol have caused it, the question 16:59:28
5 is going to be did Baycol cause it, given all these other 16:59:33
6 potential causes out there. And the individual causation 16:59:37
7 questions absolutely overwhelm any common question. The 16:59:41
8 courts recognize that it is not proper to certify a general 16:59:46
9 causation class where there are individual causation issues 16:59:51

10 that, in fact, are the core of the dispute. 16:59:55
11 Here's a list of some of those cases. Some of 17:00:05
12 them are cases that the Plaintiffs rely on for other 17:00:07
13 reasons. Some are cases that we rely on, but they all held 17:00:13
14 that where an individual causation is the real dispute in 17:00:20
15 the cases, it doesn't make sense to have certification of a 17:00:22
16 general causation class. Agent Orange, Paxil, Harding, 17:00:27
17 Tetracycline, Arch, Emig, Mertens, they all agree. 17:00:33
18 When I think about this general causation, 17:00:39
19 they've got Rhabdo, fine, not an issue, aches and pains on 17:00:42
20 the label. And then I think what else is going to be in 17:00:46
21 the general causation trial. And it's not an idle thought 17:00:49
22 because -- excuse me. Here we go. I looked through their 17:00:56
23 complaint in their briefs and what they said about general 17:01:06
24 causation, because I'm trying to figure out what is it that 17:01:10
25 we might be trying. What is it they're going to say was

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1 caused by Baycol other than Rhabdo and aches and pains, and 17:01:17
2 they really don't pin it down. They say all person, you 17:01:21
3 know, the complaint says all persons who were physically 17:01:24
4 injured as a result of taking Baycol. That's their injury 17:01:29
5 class. So, if we are going to hold them true to their 17:01:32
6 word, then, if we're going to have general causation, are 17:01:36
7 we going to have general causation on all of these sore 17:01:42
8 thumbs, you nose, decreased urine output, sore elbow. They 17:01:46
9 are all in the class, and we don't have any idea of what 17:01:53

10 would be tried. 17:01:59

11 Similarly, they didn't limit it to their brief. 17:01:59

12 They didn't limit it to Rhabdo where there is no dispute. 17:02:08

13 They didn't limit it to aches and pains. They said they 17:02:08

14 have a personal injury class of all persons who claim 17:02:13

15 physical injury caused by Rhabdo -- Baycol, I'm sorry, and 17:02:17

16 the common issue proposed is whether Baycol causes injury. 17:02:22

17 That's how they framed it in their brief. 17:02:27

18 Now, we can go into that trial and say, yes, if 17:02:32

19 causes mean can cause, we'd probably get the court to agree 17:02:34

20 to rewrite the question so it's whether Baycol can cause 17:02:39

21 injury rather than causes injury. And then we would say, 17:02:43

22 good, we can all go home and answer that question yes. And 17:02:48

23 then we'll give that verdict to Ms. Swearengin and send her 17:02:53

24 back to wherever she came from and we'll have a real trial 17:02:56

25 over whether her claimed injuries were caused by Baycol. 17:03:01

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1 And this trial isn't going to mean anything to her. This 17:03:05

2 general causation trial. 17:03:09

3 The -- just to remind the court, you know, here 17:03:17

4 are the kinds of injuries that the Plaintiffs were -- the 17:03:24

5 Plaintiffs themselves are saying are caused by Baycol and 17:03:28

6 all of these, presumably, I mean they are class in any 17:03:32

7 injury. So, just picking this tiny selection of 17:03:40

8 Plaintiffs, I guess we would have evidence here in 17:03:44

9 Minnesota on whether Baycol can cause each one of these 17:03:46

10 things which would be a colossal waste of time. And then 17:03:51
11 we turn around and go back to all of their hometowns and we 17:03:56
12 try the real case. Okay, let's say it can cause sinusitis 17:04:00
13 and did it cause sinusitis. Or do we need to look at Mr. 17:04:06
14 Hendricks' medical records and find out that he had it long 17:04:13
15 before he took Baycol and it's caused by something else. 17:04:16
16 And then there are real problems in terms of the 17:04:19
17 end game here in terms of what happens after the class 17:04:22
18 trial. And I do try a lot of cases, so I tend to think in 17:04:26
19 intensely practical terms about what happens then. We have 17:04:35
20 this trial that they are proposing, and I think to myself, 17:04:37
21 what happens to Delores Cantor. Delores Cantor is a member 17:04:42
22 of a class and we had a trial and the trial determined that 17:04:51
23 Baycol can cause Rhabdo, and Baycol can cause aches did 17:04:54
24 pains. And now we go back to wherever Delores Cantor is 17:05:01
25 from and is she estopped from arguing that Baycol can cause 17:05:07

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1 these other things because it wasn't put in the class 17:05:12
2 trial. She's, after all, a class member bound by the 17:05:14
3 judgment about what injuries are caused by Baycol, and they 17:05:17
4 didn't prove that her injuries could be caused by Baycol. 17:05:22
5 So, is that res judicata, and do we get to take that back 17:05:26
6 to wherever she lives and say, too bad for you, it should 17:05:33
7 have been litigated along with the other issues as to what 17:05:37
8 injuries Baycol can cause. That would be nice for us if 17:05:40
9 that were the result, but my guess is that there would be 17:05:46

10 judges out there who would say no, you were not going to 17:05:51
11 get the benefit. You are not going to get some kind of res 17:05:54
12 judicata benefit just because the class action lawyers 17:05:59
13 didn't do anything about Ms. Cantor and didn't put any 17:06:03
14 evidence in about her injuries. She gets to try her own 17:06:05
15 case.
16 So, where does that leave us? Let's say we win 17:06:09
17 one of these general causations, instead of limiting it to 17:06:14
18 aches and pains of Baycol, they throw in some other 17:06:17
19 injuries and we win. We still go back to all of these 17:06:20
20 hometowns and try the real life cases where the people say, 17:06:24
21 yes, that's fine but that wasn't my injury. Cardiac 17:06:30
22 myopathy, you won on cardiac myopathy, Bayer. You don't 17:06:36
23 cause cardiac myopathy. I don't have cardiac myopathy. 17:06:36
24 The thing that I have that looks a little bit like cardiac 17:06:42
25 myopathy. In fact, that's something else. It's not really

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1 cardiac myopathy. And you don't have a judgment that's 17:06:48
2 going to be preclusive against me on that, let alone on 17:06:50
3 memory loss or reddish lesions. So, we don't stand to get 17:06:54
4 any kind of benefit at all from winning one of these 17:07:03
5 trials. 17:07:06
6 As I said, the idea that other judges hearing 17:07:09
7 individual cases of class members are going to give any 17:07:14
8 sort of preclusive effect in our favor, I think is 17:07:16
9 exceedingly unlikely, and that the easiest thing in the 17:07:23

10 world for a skilled lawyer to plead around whatever 17:07:27
11 favorable verdict we got. And we are not going to get a 17:07:32
12 verdict that says we don't cause Rhabdo because we wouldn't 17:07:36
13 ask for one. And we get to these other injuries, any 17:07:40
14 injury we win on can be redescribed as a different injury. 17:07:45
15 And we try that case back in Canton, Ohio. 17:07:49
16 The same kind of unfairness problems, and I don't 17:07:54
17 mean to be a whiner about it, Judge, but after all, Rule 1 17:07:58
18 does say the just, speedy and inexpensive resolution. The 17:08:02
19 same kind of fairness problems plague their general 17:08:07
20 liability class. I've been talking now about their 17:08:10
21 causation, general causation class, but then they say we 17:08:14
22 got this general liability class, also. And I can put the 17:08:21
23 timeline up again. We're going to -- I don't know how in 17:08:24
24 the world that can possibly work. In fact, I will put it 17:08:28
25 up. 17:08:32

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1 You're not going to get a verdict that says was 17:08:36
2 Baycol negligent in the design, testing and marketing -- 17:08:41
3 I'm sorry, was Bayer neglect in the design, testing and 17:08:48
4 marketing of Baycol because, when, what dose, what period of 17:08:52
5 time. This is not a plant explosion. It's not a boat 17:09:00
6 sinking, even if it did spill a lot of oil. It's a course 17:09:06
7 of conduct that differed over time where they say there's 17:09:10
8 increasing levels of culpability. So, I think it's just 17:09:15
9 incorrect. I think you can answer a question like that. 17:09:19

10 But then they posed some more specific questions. 17:09:25
11 Did Bayer lie to the FDA? They posed a bunch of loaded 17:09:29
12 questions, and that is kind of beside the point because if 17:09:36
13 we ever did have one of these, I'm confident that Your 17:09:39
14 Honor wouldn't let them write all the questions. But let's 17:09:43
15 take, did Bayer lie to the FDA? And let's said we win that 17:09:46
16 case. We did not lie to the FDA. We could get yes answers 17:09:50
17 in our favor all or almost all of these questions that they 17:09:58
18 pose. And then we would go back and the liability trials 17:10:02
19 aren't going to go away. The liability theories are going 17:10:06
20 to be recast. The good lawyer, and they are really good 17:10:10
21 lawyers out there -- the good lawyer is going to say, lie 17:10:15
22 to the FDA. My case is not about lying to the FDA. My 17:10:20
23 case is about the fact that your detail man from Woodlawn, 17:10:27
24 Illinois came and visited the doctor, and your detail man 17:10:32
25 told the doctor things that weren't true. Told the doctor 17:10:36

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1 things that were inconsistent with what you told the FDA. 17:10:40
2 You know, it's not enough to be up front with the FDA if 17:10:43
3 your detail man is lying to the doctors. We get no 17:10:49
4 benefit, zero, by winning on these issues that they pose. 17:10:53

5 I wrote on my memo, my last subject, but it's not 17:11:00
6 my last subject because I added one when Your Honor asked 17:11:03
7 the question about what's the trial plan. So, my second to 17:11:08
8 the last subject is medical monitoring. 17:11:12

9 The Plaintiffs cannot avoid the myriad of 17:11:16

10 individual questions posed by resort to a medical 17:11:19
11 monitoring class. I want to put up for you, Your Honor, 17:11:25
12 what they say the standards are for medical monitoring. 17:11:30
13 This is from their brief. I think it's their opening 17:11:40
14 brief. Anyway, one of their briefs, and they're talking 17:11:47
15 about medical monitoring, they being the Plaintiffs. And 17:11:49
16 down in Footnote 49, they set forth the medical monitoring 17:11:53
17 elements under Pennsylvania law. So, it may have been back 17:12:03
18 when they were saying everything was Pennsylvania. 17:12:08
19 But, anyway, let's just take a look at 17:12:10
20 Pennsylvania as representative, because if it's not, then 17:12:16
21 that's a whole different issue. We got a whole bunch of 17:12:18
22 different laws on medical monitoring with different 17:12:21
23 elements. That means that common issues do not 17:12:24
24 predominate. But let's just pretend that the law of 17:12:29
25 Pennsylvania governs on medical monitoring. 17:12:33

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1 One of the things I wanted to point out here is 17:12:36
2 that according to the case cited by the Plaintiffs, there 17:12:37
3 has to be exposure greater than normal background levels to 17:12:50
4 a prudent hazardous substance caused by Defendants' 17:12:58
5 negligence. So, incorporated into the medical monitoring 17:13:07
6 cause of action is a cause of action for negligence, and 17:13:12
7 all of the individual questions that we talked about in 17:13:20
8 terms of the law on negligence in different states, and 17:13:25
9 negligence win along our time line and all of myriad of 17:13:29

10 individual questions, different state laws, different 17:13:34
11 doses. You know, there is one story with .2. There's 17:13:36
12 another story with .8 in terms of what kind of a case 17:13:41
13 somebody can make on negligence. Different time periods. 17:13:46
14 One story before a study came out, a different story after 17:13:50
15 the study came out. Different warnings were given. If 17:13:54
16 it's a negligence failure to warn, that's why somebody was 17:13:56
17 exposed, then that's one story. If it's the day before the 17:13:59
18 label came out saying don't take Gemfibrozil when you're 17:14:05
19 taking Baycol, the warning against that, it's another story 17:14:10
20 if it comes out the day after. And it's still a different 17:14:14
21 story if it comes out after the next label is released, 17:14:19
22 not just a warning, but a contraindication. That's a 17:14:24
23 different story still if it comes out after the dear doctor 17:14:28
24 letter is sent out. So, there's all these individual 17:14:29
25 questions. Individual questions, incidentally, are going 17:14:32

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1 to include, I haven't spent much time on this, but believe 17:14:35
2 it or not, but the individual questions would also include 17:14:40
3 the different levels of knowledge of the doctors. That's 17:14:44
4 the learned intermediary concept that comes into play in 17:14:49
5 most states. And if the doctors know from medical 17:14:54
6 literature and elsewhere about all of the risks, and if the 17:14:56
7 doctors have an understanding about different levels of 17:14:59
8 risks with different statins, then that's all going to come 17:15:03
9 into play. Then and all of these things all going to be 17:15:07

10 swept into the case because they had to make out a 17:15:12
11 negligence case in order to make out a medical monitoring 17:15:15
12 case. 17:15:20
13 Another couple of things I want to focus on here. 17:15:23
14 Item Number 6, we're talking now, of course, about whether 17:15:29
15 medical monitoring is appropriate for class treatment, and 17:15:32
16 one of the things, you know, to look at is what are the 17:15:40
17 elements of medical monitoring. And one of the elements of 17:15:41
18 medical monitoring is that the prescribed monitoring 17:15:45
19 regimes is different from that normally recommended in the 17:15:54
20 absence of the exposure. 17:15:54
21 So, what we have here are the class 17:15:54
22 representatives for the medical monitoring class. All -- 17:15:58
23 let me back up because I've got several points to make. 17:16:12
24 First of all, their expert, Dr. Kaysen, actually never 17:16:15
25 looked at the medical records of the class representatives 17:16:22

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1 for the medical monitoring class. He testified under oath 17:16:28
2 that one thing he did not examine was the medical records 17:16:32
3 of the people that the class action lawyers hold forth as 17:16:38
4 representative of the medical monitoring class. So, he's 17:16:42
5 never looked at the medical records of the class reps. 17:16:46
6 Well, we have. And it ends up as we walk through on the 17:16:50
7 time line when I clicked on each one, there were five of 17:16:55
8 them, and all five of the class representatives in the 17:16:59
9 medical monitoring class already got the prescribed 17:17:03

10 monitoring regime, and they got it because it was normally 17:17:12
11 recommended for other reasons. So, the only people they 17:17:18
12 have sent forth as representative of the class have already 17:17:22
13 gotten the monitoring that their expert says they should 17:17:25
14 get. And they got it for reasons having nothing to do with 17:17:30
15 their exposure to Baycol. So, that's an important element 17:17:34
16 to consider. 17:17:39

17 We also looked at all of the other class 17:17:46
18 representatives. Again, this was the time line with the 17:17:49
19 different colored bars, and I think Your Honor will recall 17:17:53
20 that when you look at medical monitoring, personal injury 17:17:56
21 or refund, every single person that they hold forth as a 17:18:03
22 representative of any class received the blood pressure and 17:18:07
23 creatinine tests for reasons having nothing to do with 17:18:15
24 their use of Baycol. It's the prescribed monitoring regime 17:18:18
25 that they have come up with is exactly the same as what the 17:18:25

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1 class members get in their normal medical treatment having 17:18:30
2 nothing to do with Baycol. 17:18:34

3 They then picked 30 or 31 Plaintiffs who are not 17:18:37
4 class reps, one of the lawyers picked out 30 or 31 17:18:44
5 Plaintiffs from their files. We don't know how they picked 17:18:49
6 them. They file an affidavit, but we don't get to cross 17:18:53
7 examine the lawyers about how they went about selecting. 17:18:57
8 And I found over the years that it's pretty interesting to 17:18:59
9 find out how people select a sample. But we don't know. 17:19:03

10 Anyway, they picked 30 or 31 who aren't class reps. Their 17:19:09
11 doctors looks at them. Only 5 of the 31 does he say are 17:19:15
12 in need of medical monitoring. He looks at the 5 and he 17:19:18
13 says these 5 should get a blood pressure test and a 17:19:25
14 creatinine test. The other 25 or 26 don't even need the 17:19:28
15 tests. Well, all 5 of the people that he said should get a 17:19:33
16 blood tests or creatinine test, just like all the class 17:19:43
17 reps, they already got it. All 5 of the people that he 17:19:46
18 says should receive a test have received a test, and he 17:19:51
19 doesn't pretend that they should receive a second test. 17:19:56
20 So, the medical monitoring -- well, let's go on 17:20:00
21 to the last factor. The medical monitoring class, Your 17:20:06
22 Honor is a way to set up a -- well, I'm not going to say 17:20:12
23 that. 17:20:13
24 Last point, Point 7. The prescribed monitoring 17:20:16
25 regimen is reasonably necessary according to contemporary 17:20:23

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1 scientific principles. So, we're not just going to do this 17:20:28
2 on a lark. We're not going to just spend an enormous 17:20:33
3 amount of money and create a big pool of legal fees when 17:20:37
4 the test isn't necessary according to contemporary 17:20:40
5 scientific principles. When you listened to Mr. Arsenault 17:20:46
6 this morning, he basically said that it's generally 17:20:49
7 accepted in the scientific community that medical 17:20:53
8 monitoring is appropriate for Baycol. At least that was 17:20:58
9 the message that I heard from him. Their paid expert's 17:21:01

10 testimony is to the contrary on that. I've got to switch 17:21:06

11 over to this other computer for a moment, Your Honor. 17:21:10

12 This is Dr. Kaysen. He was hired by them to 17:21:51

13 develop the medical monitoring protocol. And one of the 17:21:53

14 questions is is the prescribed monitoring regime reasonably 17:21:55

15 necessary according to contemporary scientific principles, 17:22:01

16 and here's his testimony. 17:22:06

17 (Video showing) 17:22:19

18 THE COURT: Would you start this over. 17:22:31

19 MR. BECK: Yes. Your Honor, not only will I, I 17:22:31

20 was going to no matter what. 17:22:36

21 THE COURT: The reason why is I want to make sure 17:22:37

22 we keep the ventilation going because they shut it off at a 17:22:40

23 certain time. 17:22:47

24 MR. BECK: Are you suggesting there's some hot

25 air that's -- (Laughter)

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1 THE COURT: I'm suggesting that GSA controls 17:22:49

2 this building. They want to save on the heating bill. 17:22:52

3 MR. BECK: Here's Dr. Kaysen. Again, the context 17:22:57

4 is whether the prescribed monitoring regime is reasonable 17:23:01

5 necessary according to contemporary scientific principles. 17:23:03

6 (Video showing)

7 THE COURT: Let's take a stretch break. Mr. 17:34:30

8 Beck, if you hear a thump in the back behind you, Mr. 17:34:30

9 Goldser is falling over because of a lack of sleep because 17:34:39

10 he had a flight from Maui, and he may fall over for a lack 17:34:41
11 of sleep. (Laughter). 17:34:53

12 MR. BECK: I'm trying to remember whether state 17:34:53
13 of the art evidence is admissible in Maui. 17:34:55

14 MR. GOLDSER: I know Your Honor gave me an 17:35:01
15 opportunity to serve, and I'm delighted to do so. 17:35:03

16 THE COURT: I sent out a message that he would 17:35:08
17 have to stay until ten o'clock to vacuum. (Laughter). 17:35:10

18 MR. BECK: Well, Your Honor, believe it or not, 17:35:15
19 we are in the home stretch. 17:35:18

20 THE COURT: What we are going to do is stop when 17:35:20
21 you are finished and we'll start up tomorrow because the 17:35:22
22 status conference is not going to be that long. 17:35:25

23 MR. BECK: I really appreciate the patience and 17:35:31
24 forbearance you have shown today, and I'm in the home 17:35:34
25 stretch. 17:35:45

1 THE COURT: My comments about Mr. Goldser had 17:35:45
2 nothing to do with your presentation. I'm just giving Mr. 17:35:45
3 Goldser a hard time because I would be coming back from 17:35:48
4 Hawaii. 17:35:51

5 MR. GOLDSER: I have thoroughly enjoyed Mr. Beck. 17:35:53

6 MR. BECK: Well, we are on Dr. Kaysen. He's 17:35:58
7 their medical monitoring expert, and the question that 17:36:03
8 we're talking about is whether the prescribed monitoring 17:36:04
9 proceedings are reasonably necessary according to 17:36:16

10 contemporary scientific principles. We saw the first clip,

11 and here's the second clip.

12 (Video played)

13 MR. BECK: And the last clip. 17:37:41

14 (Video played)

15 MR. BECK: In sum, Your Honor, on the medical 17:38:20

16 monitoring side, we have a class, all of whose 17:38:23

17 representatives have already gotten the prescribed regime 17:38:28

18 for reasons having nothing to do with Baycol, and then we 17:38:32

19 have a complete absence of any sort of consensus that 17:38:36

20 anyone should get it because of Baycol. 17:38:43

21 Now, the last -- truly the last issue that I want 17:38:49

22 to discuss is the issue that Your Honor raised early on 17:38:52

23 about what would happen in this trial you want me to have. 17:38:59

24 And I think the question also included a component about 17:39:05

25 what's going to happen in the other trials, the trials when 17:39:11

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1 they remand these cases or if there is a class action that 17:39:17

2 obviously would include people who are in state courts as 17:39:22

3 well. What happens in the state courts after we have this 17:39:25

4 trial that you envision, what's the plan. And I was 17:39:29

5 listening for a plan, and I think that what I heard were 17:39:39

6 very skillful lawyers who did their best to talk about a 17:39:46

7 lot of things, but they didn't talk about a plan. They 17:39:57

8 didn't say, well, here's what we'll do. Here's how long 17:39:59

9 the case will take. Here's the issues that'll be 17:40:01

10 presented. Here's the way it'll work. Here's how we'll be 17:40:04
11 able to frame them. Here's how we are going to handle the 17:40:08
12 jury instructions from 51 different jurisdictions. Here's 17:40:13
13 how we can do a manageable verdict form, that kind of 17:40:15
14 thing.

15 It's interesting because when I was in Boston on 17:40:17
16 trial up until yesterday, and when I came into town and I 17:40:20
17 was talking with the members of our team, I asked the same 17:40:27
18 question, a little different way. I had just gotten back 17:40:32
19 from this trial in Boston. It was a patent case, and the 17:40:38
20 only issue was infringement. Didn't involve willful 17:40:44
21 infringement, didn't involve validity, didn't involve 17:40:47
22 damages that had been bifurcated and trifurcated and 17:40:50
23 quarterfurcated down to just infringement. And the Judge 17:40:54
24 said he wanted a special verdict form involving three 17:40:58
25 claims from two different patents. And the special verdict 17:41:03

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1 form that the plaintiff submitted had 328 questions and 17:41:05
2 covered a hundred pages. 17:41:07

3 Now, he didn't do a very good job on the special 17:41:09
4 verdict form. But even doing a good job on that case, the 17:41:14
5 special verdict form was an enormous challenge. So I asked 17:41:20
6 Susan Weber and others of my colleagues, I said, I'd like 17:41:23
7 to see some special verdict forms that were actually used 17:41:26
8 in cases where classes were certified on common issues 17:41:30
9 where if it's a pharmaceutical product or some kind of 17:41:36

10 situation where there is a course of conduct, there is 17:41:43
11 variations in the product or different product over time, 17:41:46
12 different communications to the public where you have this 17:41:48
13 kind of continuum of facts where they claim life gets worse 17:41:52
14 and worse and worse, how in the world do you pose a special 17:41:58
15 verdict and what kind of instructions. So, and I was 17:42:05
16 especially interested in how do you handle a situation like 17:42:09
17 that when there are multiple causes of action, and the 17:42:11
18 causes of action are governed by 51 different state laws 17:42:19
19 because to me the issues are a mind boggling one. So, I 17:42:24
20 wanted to see how it's been done. And the answer as best 17:42:31
21 as I've been able to find out is that almost nobody ever 17:42:34
22 does it in real life. 17:42:38
23 What happens is that sometimes -- well, when 17:42:41
24 Plaintiffs move for class certification, they promise that 17:42:43
25 a trial plan -- and sometimes a trial plan can be put 17:42:51

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1 together because it's not this kind of case. It's the 17:42:54
2 train fell off the tracks and the fumes were released and 17:42:59
3 everybody was exposed to the same thing at the same time. 17:43:04
4 But in a case like this, people talk about, well, we'll be 17:43:08
5 able to do a trial plan. Lawyers are creative and we all 17:43:15
6 work together in the right spirited kind of keep in mind 17:43:20
7 rule one. We'll be able to come up with trial plan. And 17:43:22
8 let's not look at the glass as half empty. Let's look at 17:43:26
9 it as half full. And they make arguments for the trial 17:43:29

10 plan like that and sometimes judges agree with them. And 17:43:31
11 they talk about I think we'll be able to do a trial plan. 17:43:36
12 We'll be able to do special verdicts. We'll be able to do 17:43:37
13 instructions. I have a lot of faith in the jury system. I 17:43:37
14 think the jurors are smart enough to understand 17:43:40
15 instructions. 17:43:44
16 But then what happens is, at least in cases like 17:43:45
17 this, we never see any plans get implement. We see people 17:43:48
18 talk in the abstract about how they can do it. We don't 17:43:55
19 see plans, and we certainly don't see the implementation of 17:43:59
20 plans in cases that have this kind of intersection of so 17:44:03
21 many different competing legal jurisdictions on multiple 17:44:08
22 causes of action with this sort of continuum situation 17:44:13
23 where you have different slices of fact that are going to 17:44:16
24 be relevant to different people's causes of action. In a 17:44:19
25 situation like that, you know, maybe tomorrow morning 17:44:23

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1 they'll show us a plan, but I haven't seen one. 17:44:28
2 What happens, in fact, is in situations like 17:44:31
3 that, historically, certification of a class leads to 17:44:33
4 settlement because the Defendants cannot afford to let the 17:44:42
5 company, even if they think they're right because there is 17:44:46
6 this enormous looming potential disaster, and that's the 17:44:52
7 leverage that class action lawyers have, and it's the 17:44:58
8 leverage that they seek when they want to get a class 17:45:02
9 certified because their focus is not, frankly, on how are 17:45:05

10 we going to try this case. Their focus is how are we going 17:45:09

11 to get a class certified so we never have to try this case. 17:45:13

12 Historically, defendants have made an economic 17:45:20

13 calculation and said we can't afford to take the risk. We 17:45:23

14 can't afford to bet the company. 17:45:29

15 As Professor Miller said, things change. And 17:45:36

16 while Defendants have been saying to themselves for years, 17:45:44

17 we can't afford the class trial. Life has changed a little 17:45:47

18 bit recently, and now Defendants are starting to think we 17:45:52

19 can't afford a class settlement. 17:45:59

20 Diet drugs, one of their cases that they rely on 17:46:03

21 heavily is an excellent example for Your Honor to follow, 17:46:11

22 one of Professor Miller's examples. 17:46:15

23 After class certification, the defendant felt 17:46:19

24 compelled to settle. I'm sure this is American Home 17:46:23

25 Products. I'm sure they felt that they were paying an 17:46:26

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1 enormous amount of money to get rid of a lot of claims, 17:46:29

2 only a very few of which involved real injuries, but it was 17:46:35

3 the cost of doing business to get rid of the other claims 17:46:40

4 because they couldn't get out of that litigation. They 17:46:42

5 couldn't buy peace. They couldn't put it behind them 17:46:46

6 unless they came up with a settlement that paid everybody 17:46:51

7 off. So, I think the amount was \$4,000,000,000 that they 17:46:55

8 paid hoping to get global peace. As I said, I'm sure they 17:47:00

9 felt they overpaid, but nevertheless, I think that's the 17:47:08

10 amount they paid. 17:47:11

11 But all they did was buy war and not peace. 17:47:14
12 People that have lousy cases, in our case, the aches and 17:47:17
13 pains ones, the cataract cases, the decreased urine cases, 17:47:23
14 they all jumped in and took their piece of the 17:47:29
15 \$4,000,000,000. And the people who's real injuries opted 17:47:33
16 out. And a whole bunch of people who did not have real 17:47:37
17 injuries opted out because their lawyers figured that these 17:47:41
18 guys are willing to pay \$4,000,000,000 for global peace. 17:47:46
19 The people who are willing to hold out and play poker, 17:47:48
20 we'll get even more than our share of the \$4,000,000,000. 17:47:53
21 And sure enough \$8,000,000,000 later, American Home 17:47:56
22 Products was on the brink of bankruptcy, finally, and only 17:48:02
23 because there was so little meat left on the carcass to 17:48:06
24 pick over was there a global resolution that put those 17:48:10
25 claims to rest. 17:48:16

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1 Well, we agree with Professor Miller that that 17:48:18
2 case is instructive. But what's instructive to us is what 17:48:26
3 happened to the defendant after certification and 17:48:32
4 settlement rather than the analysis that went into the 17:48:36
5 certification opinion. And we have decided as we have said 17:48:40
6 before that we are not going to cave in on cases that we 17:48:43
7 think involve no injury in an attempt to buy global peace. 17:48:50
8 And you've heard that from us when we talked about our 17:48:57
9 settlement approach when we were down in Louisiana. I 17:49:01
10 stood up and announced it and that may have been the first 17:49:05

11 time we publicly announced it. And I said we wanted to be 17:49:07
12 reasonable and, in fact, want to be generous with those who 17:49:12
13 have been injured. We don't want to argue about things 17:49:15
14 like causation, concomitant causes or comparative fault. 17:49:17
15 If there is a contemporaneous case of Rhabdo with Baycol 17:49:24
16 use, we want to settle it. 17:49:28
17 Now, so far we have settled at last count about 17:49:31
18 430 cases. We have a lot more cases under discussion, and 17:49:34
19 sometimes we are able to agree with Plaintiffs' lawyers on 17:49:40
20 what the cases are worth, and sometimes we are not able to 17:49:44
21 agree. And those cases are going to go to trial. We're 17:49:46
22 going to learn something from those cases. And the 17:49:50
23 Plaintiffs' bar is going to learn something from those 17:49:52
24 cases. And once we have several of those cases under our 17:49:56
25 belt, and, frankly, we're playing in their home courts, but 17:50:00

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1 once we -- and I can't do anything about that. Once we get 17:50:04
2 several cases under our belt, everybody will be able to 17:50:06
3 take a deep he breath and say, okay, what are the value of 17:50:09
4 these cases. And, then, for the people who you suffered 17:50:13
5 injury, either they'll figure out that the value is lower 17:50:17
6 than they hoped, or we might figure out it's higher, or we 17:50:20
7 might say we would spot out. But we'll continue to talk to 17:50:26
8 Plaintiffs' lawyers and settle the cases where people were 17:50:30
9 hurt, and we're not going to settle the cases where people 17:50:32
10 were not hurt. We are not going to settle the vast 17:50:35

11 majority, whether I'm right or wrong about 99 percent or 96 17:50:40
12 or 90 percent, we're not going to settle the cases where 17:50:43
13 people bought our cases, it lowered their cholesterol and 17:50:47
14 they suffered no side effects and they benefitted rather 17:50:53
15 than were hurt. We are not going to pay money for those 17:50:56
16 cases unless some jury tells us that we have to. 17:51:00
17 We have the same plan for trial. We're going to 17:51:05
18 try to resolve the cases that have real injuries. We're
19 going to try to settle those right up to the courthouse 17:51:10
20 steps and during trial, and we'll be talking to juries 17:51:13
21 about what's reasonable compensation. But we're going to 17:51:15
22 be defending ourselves when people did not suffer and 17:51:18
23 instead benefitted from our product. And the reason we're 17:51:21
24 going to do that is because I, too, believe in the jury 17:51:31
25 system. And I believe that when juries hear these cases 17:51:31

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1 that if somebody benefitted from our product and was not 17:51:38
2 hurt a jury is not going to say they deserve a lot of 17:51:41
3 money. 17:51:46
4 And one of the reasons that we are resisting 17:51:46
5 class certification is because the intended end gain of 17:51:51
6 class certification is us paying a lot of money to people 17:51:58
7 who were not hurt and who, in fact, benefitted from our 17:51:58
8 medicine. 17:52:02
9 So, especially given our resolve, the Court's 17:52:04
10 question about what happens at trial becomes very, very 17:52:10

11 important because unlike in most cases where common issue 17:52:14
12 classes have been certified, here they're going to be 17:52:22
13 trials. 17:52:25
14 What would be a real-life trial like in this 17:52:29
15 case? We would have an incomprehensible verdict form. 17:52:33
16 Professor Miller, who acknowledges that he's been in 17:52:42
17 academia for several decades, allowed us how the verdict 17:52:50
18 form might take several pages. It's going to take a lot 17:52:54
19 more than several pages, Your Honor. 17:53:01
20 When we have each of those relevant slices of 17:53:06
21 time, however, finally they end up getting sliced, the laws 17:53:10
22 of 51 states and 7 or 8 causes of action under the laws of 17:53:15
23 51 states, that's a mind boggling task for a jury to try to 17:53:19
24 answer those kinds of questions. And I try a lot of jury 17:53:27
25 cases and I have enormous respect for juries, but I don't 17:53:30

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1 hold out any illusions that a jury can handle that kind of 17:53:35
2 a task. And one of the reasons they couldn't is because 17:53:40
3 juries have to be instructed on these special verdict 17:53:43
4 forms, and the instruction would be unparalleled nightmare. 17:53:49
5 I've touched on some of this before. 17:53:53
6 Here we have a jury of 12 Minnesotans, and we 17:53:56
7 have this book like special verdict form and they're told, 17:54:01
8 when you're applying Virginia law, you must consider this 17:54:06
9 factor, Factor X. But when you're applying Illinois law, 17:54:11
10 it's up to you whether to consider Factor X. When you're 17:54:16

11 applying the law of Arizona, you have to pretend that you 17:54:21
12 never heard these instructions about Factor X because it's 17:54:25
13 reversible error for me to talk about Factor X with you. 17:54:30
14 And you're applying the law of Montana, you have to forget 17:54:34
15 not only what I said about Factor X, you have to forget 17:54:40
16 Factor X because it's reversible error to admit that 17:54:47
17 evidence in support of this cause of the action. 17:54:49
18 Those are not, I think the phrase was, imaginary 17:54:52
19 horrors. Those are not imaginary horrors. People who try 17:54:59
20 cases for a living and try and defend negligence cases and 17:55:00
21 product liability cases and insufficient warning cases, we 17:55:07
22 appreciate that there are sometimes subtle, but 17:55:10
23 nevertheless substantial differences from state to state in 17:55:14
24 terms of the elements of the cause of action. And then 17:55:18
25 they get more subtle because really the law of Minnesota, 17:55:21

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1 when you think about it, includes not just the standard 17:55:28
2 verdict form, but it includes the standard instructions 17:55:32
3 because they give meaning and life to the verdict form and 17:55:36
4 they evolve over a long period of time and are subject to 17:55:39
5 countless lawsuits where they get refined, and courts 17:55:42
6 appoint commissions to come up with model jury 17:55:47
7 instructions, states take this seriously and they take it 17:55:52
8 personally if that's possible to do by a state. 17:55:55
9 So, there is no way in the world that common 17:55:58
10 issues could be severed from the overwhelming predominant 17:56:00

11 individual issues. And whatever ended up getting sliced 17:56:09
12 off at the end of the sausage, there is no realistic plan 17:56:14
13 that could be proposed by Plaintiffs to handle it in this 17:56:19
14 case. And that says nothing about what happens when we go 17:56:21
15 back to the other trials -- when we go back to the other 17:56:26
16 courts. 17:56:30

17 Whatever we come up with, people are going to 17:56:31
18 look at and it's going to be so finely sliced and so finely 17:56:35
19 tuned, that any plaintiff whose disappointed in any one of 17:56:39
20 the answers pleads around it and we are off to the races. 17:56:45

21 Thank you again nor your patience, Your Honor. 17:56:50

22 THE COURT: Thank you. We'll adjourn until 9:30 17:56:53
23 tomorrow morning. 17:56:57

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1 REPORTER'S CERTIFICATE
2 I, Brenda E. Anderson, Official Court Reporter,
3 in the United States District Court for the District of
4 Minnesota, do hereby certify that the foregoing transcript
5 is a true and correct transcript of the proceedings in the
6 above-entitled matter.
7
8
9 CERTIFIED: _____
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Brenda E. Anderson, RPR

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