Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ASTHENIA	≤63 Days (All)	175	2 (1%)	0.3331	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	1 (100%)	0	0
BACK PAIN	≤63 Days (All)	175	5 (3%)	0.8426	5	3 (60%)	2 (40%)	0	0
	≤49 Days (Group 1)	71	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	72	3 (4%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
PALLOR	≤63 Days (All)	175	1 (<1%)	0.1829	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	1 (100%)	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	178	173 (97%)	0.3309	560	154 (28%)	223 (40%)	183 (33%)	0
	≤49 Days (Group 1)	72	69 (96%)		218	63 (29%)	86 (39%)	69 (32%)	0
	50-56 Days (Group 2)	54	54 (100%)		174	55 (32%)	65 (37%)	54 (31%)	0
	57-63 Days (Group 3)	52	50 (96%)		168	36 (21%)	72 (43%)	60 (36%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	123 (69%)	0.6317	230	105 (46%)	87 (38%)	38 (17%)	0
	≤49 Days (Group 1)	72	48 (67%)		81	40 (49%)	30 (37%)	11 (14%)	0
	50-56 Days (Group 2)	54	40 (74%)		77	40 (52%)	26 (34%)	11 (14%)	0
	57-63 Days (Group 3)	52	35 (67%)		72	25 (35%)	31 (43%)	16 (22%)	0
DIARRHEA	≤63 Days (All)	178	32 (18%)	0.6040	34	15 (44%)	16 (47%)	3 (9%)	0
	≤49 Days (Group 1)	72	11 (15%)		11	5 (45%)	5 (45%)	1 (9%)	0
	50-56 Days (Group 2)	54	12 (22%)		14	7 (50%)	6 (43%)	1 (7%)	0
	57-63 Days (Group 3)	52	9 (17%)		9	3 (33%)	5 (56%)	1 (11%)	0
NAUSEA	≤63 Days (All)	178	106 (60%)	0.9440	136	63 (46%)	46 (34%)	27 (20%)	0
	≤49 Days (Group 1)	72	43 (60%)		49	26 (53%)	17 (35%)	6 (12%)	0
	50-56 Days (Group 2)	54	33 (61%)		46	24 (52%)	13 (28%)	9 (20%)	0
	57-63 Days (Group 3)	52	30 (58%)		41	13 (32%)	16 (39%)	12 (29%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	**(cont.)**								
VOMITING	≤63 Days (All)	178	54 (30%)	0.3297	60	27 (45%)	25 (42%)	8 (13%)	0
	≤49 Days (Group 1)	72	19 (26%)		21	9 (43%)	8 (38%)	4 (19%)	0
	50 56 Days (Group 2)	54	15 (28%)		17	9 (53%)	7 (41%)	1 (6%)	0
	57-63 Days (Group 3)	52	20 (38%)		22	9 (41%)	10 (45%)	3 (14%)	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	178	4 (2%)	1.0000	5	0	0	5 (100%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1 (2%)		2	0	0	2 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	178	4 (2%)	1.0000	5	0	0	5 (100%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1 (2%)		2	0	0	2 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	178	171 (96%)	0.4932	325	49 (15%)	136 (42%)	140 (43%)	0
	≤49 Days (Group 1)	72	69 (96%)		135	23 (17%)	56 (41%)	56 (41%)	0
	50-56 Days (Group 2)	54	53 (98%)		96	15 (16%)	39 (41%)	42 (44%)	0
	57-63 Days (Group 3)	52	49 (94%)		94	11 (12%)	41 (44%)	42 (45%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	178	171 (96%)	0.4932	321	48 (15%)	135 (42%)	138 (43%)	0
	≤49 Days (Group 1)	72	69 (96%)		132	22 (17%)	56 (42%)	54 (41%)	0
	50-56 Days (Group 2)	54	53 (98%)		95	15 (16%)	38 (40%)	42 (44%)	0
	57-63 Days (Group 3)	52	49 (94%)		94	11 (12%)	41 (44%)	42 (45%)	0
BACK PAIN	≤63 Days (All)	178	3 (2%)	0.7812	4	1 (25%)	1 (25%)	2 (50%)	0
	≤49 Days (Group 1)	72	2 (3%)		3	1 (33%)	0	2 (67%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	179	178 (>99%)	1.0000	787	284 (36%)	363 (46%)	139 (18%)	1 (<1%)
	≤49 Days (Group 1)	63	62 (98%)		250	91 (36%)	124 (50%)	34 (14%)	1 (<1%)
	50-56 Days (Group 2)	59	59 (100%)		262	87 (33%)	124 (47%)	51 (19%)	0
	57-63 Days (Group 3)	57	57 (100%)		275	106 (39%)	115 (42%)	54 (20%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.2076	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
PRURITUS	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	179	1 (<1%)	0.6480	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	22 (12%)	0.6856	30	4 (13%)	25 (83%)	1 (3%)	0
	≤49 Days (Group 1)	63	6 (10%)		8	1 (13%)	7 (88%)	0	0
	50-56 Days (Group 2)	59	9 (15%)		13	1 (8%)	11 (85%)	1 (8%)	0
	57-63 Days (Group 3)	57	7 (12%)		9	2 (22%)	7 (78%)	0	0
DIZZINESS	≤63 Days (All)	179	6 (3%)	0.6916	8	3 (38%)	4 (50%)	1 (13%)	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	59	3 (5%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
HEADACHE	≤63 Days (All)	179	18 (10%)	0.7431	22	1 (5%)	21 (95%)	0	0
	≤49 Days (Group 1)	63	5 (8%)		6	0	6 (100%)	0	0
	50-56 Days (Group 2)	59	6 (10%)		8	0	8 (100%)	0	0
	57-63 Days (Group 3)	57	7 (12%)		8	1 (13%)	7 (88%)	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	179	4 (2%)	0.2703	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	63	3 (5%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0
ANXIETY	≤63 Days (All)	179	2 (1%)	0.3302	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	63	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	179	2 (1%)	0.7667	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	144 (80%)	0.8417	241	117 (49%)	95 (39%)	29 (12%)	0
	≤49 Days (Group 1)	63	50 (79%)		78	37 (47%)	33 (42%)	8 (10%)	0
	50-56 Days (Group 2)	59	49 (83%)		82	35 (43%)	37 (45%)	10 (12%)	0
	57-63 Days (Group 3)	57	45 (79%)		81	45 (56%)	25 (31%)	11 (14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	179	2 (1%)	0.3302	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	179	23 (13%)	0.7556	24	13 (54%)	11 (46%)	0	0
	≤49 Days (Group 1)	63	9 (14%)		9	3 (33%)	6 (67%)	0	0
	50-56 Days (Group 2)	59	6 (10%)		6	4 (67%)	2 (33%)	0	0
	57-63 Days (Group 3)	57	8 (14%)		9	6 (67%)	3 (33%)	0	0
DYSPEPSIA	≤63 Days (All)	179	2 (1%)	0.2076	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	179	136 (76%)	0.6704	169	92 (54%)	53 (31%)	24 (14%)	0
	≤49 Days (Group 1)	63	46 (73%)		56	31 (55%)	17 (30%)	8 (14%)	0
	50-56 Days (Group 2)	59	47 (80%)		57	27 (47%)	22 (39%)	8 (14%)	0
	57-63 Days (Group 3)	57	43 (75%)		56	34 (61%)	14 (25%)	8 (14%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
VOMITING	≤63 Days (All)	179	39 (22%)	0.2601	44	10 (23%)	29 (66%)	5 (11%)	0
	≤49 Days (Group 1)	63	10 (16%)		11	2 (18%)	9 (82%)	0	0
	50-56 Days (Group 2)	59	13 (22%)		17	3 (18%)	12 (71%)	2 (12%)	0
	57-63 Days (Group 3)	57	16 (28%)		16	5 (31%)	8 (50%)	3 (19%)	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS	**(cont.)**								
DYSPNOEA	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	179	20 (11%)	0.2500	20	11 (55%)	7 (35%)	2 (10%)	0
	≤49 Days (Group 1)	63	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	59	7 (12%)		7	4 (57%)	2 (29%)	1 (14%)	0
	57-63 Days (Group 3)	57	9 (16%)		9	4 (44%)	4 (44%)	1 (11%)	0
ANAEMIA	≤63 Days (All)	179	19 (11%)	0.2482	19	10 (53%)	7 (37%)	2 (11%)	0
	≤49 Days (Group 1)	63	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	59	6 (10%)		6	3 (50%)	2 (33%)	1 (17%)	0
	57-63 Days (Group 3)	57	9 (16%)		9	4 (44%)	4 (44%)	1 (11%)	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	179	12 (7%)	0.0842	14	1 (7%)	3 (21%)	10 (71%)	0
	≤49 Days (Group 1)	63	1 (2%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	59	5 (8%)		6	1 (17%)	2 (33%)	3 (50%)	0
	57-63 Days (Group 3)	57	6 (11%)		6	0	1 (17%)	5 (83%)	0
BREAST DISCHARGE	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
UTERINE ATONY	≤63 Days (All)	179	2 (1%)	0.1002	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	2 (4%)		2	0	1 (50%)	1 (50%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	179	10 (6%)	0.1981	11	0	2 (18%)	9 (82%)	0
	≤49 Days (Group 1)	63	1 (2%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	59	5 (8%)		5	0	2 (40%)	3 (60%)	0
	57-63 Days (Group 3)	57	4 (7%)		4	0	0	4 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	179	174 (97%)	0.1300	472	148 (31%)	228 (48%)	95 (20%)	1 (<1%)
	≤49 Days (Group 1)	63	59 (94%)		152	49 (32%)	79 (52%)	23 (15%)	1 (<1%)
	50-56 Days (Group 2)	59	58 (98%)		152	45 (30%)	72 (47%)	35 (23%)	0
	57-63 Days (Group 3)	57	57 (100%)		168	54 (32%)	77 (46%)	37 (22%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	179	173 (97%)	0.0495	447	140 (31%)	217 (49%)	89 (20%)	1 (<1%)
	≤49 Days (Group 1)	63	58 (92%)		142	46 (32%)	73 (51%)	22 (15%)	1 (<1%)
	50-56 Days (Group 2)	59	58 (98%)		146	42 (29%)	71 (49%)	33 (23%)	0
	57-63 Days (Group 3)	57	57 (100%)		159	52 (33%)	73 (46%)	34 (21%)	0
ASTHENIA	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
BACK PAIN	≤63 Days (All)	179	7 (4%)	0.7036	9	4 (44%)	4 (44%)	1 (11%)	0
	≤49 Days (Group 1)	63	3 (5%)		5	1 (20%)	4 (80%)	0	0
	50-56 Days (Group 2)	59	3 (5%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0
FATIGUE	≤63 Days (All)	179	6 (3%)	0.2197	6	3 (50%)	2 (33%)	1 (17%)	0
	≤49 Days (Group 1)	63	3 (5%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	3 (5%)		3	1 (33%)	2 (67%)	0	0
FEVER	≤63 Days (All)	179	2 (1%)	0.7667	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
HYPOVOLAEMIA	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	179	2 (1%)	0.2076	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
PAIN	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
RIGORS	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	1028	350 (34%)	388 (38%)	264 (26%)	26 (3%)
	≤49 Days (Group 1)	29	27 (93%)		129	38 (29%)	59 (46%)	32 (25%)	0
	50-56 Days (Group 2)	73	71 (97%)		384	150 (39%)	142 (37%)	81 (21%)	11 (3%)
	57-63 Days (Group 3)	89	89 (100%)		515	162 (31%)	187 (36%)	151 (29%)	15 (3%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	191	3 (2%)	0.5453	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
RASH	≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
SKIN AND APPENDAGES DISORDERS (cont.)									
URTICARIA	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	38 (20%)	0.9103	57	11 (19%)	34 (60%)	10 (18%)	2 (4%)
	≤49 Days (Group 1)	29	5 (17%)		8	1 (13%)	6 (75%)	1 (13%)	0
	50-56 Days (Group 2)	73	14 (19%)		22	4 (18%)	14 (64%)	3 (14%)	1 (5%)
	57-63 Days (Group 3)	89	19 (21%)		27	6 (22%)	14 (52%)	6 (22%)	1 (4%)
DIZZINESS	≤63 Days (All)	191	8 (4%)	0.2868	9	1 (11%)	3 (33%)	5 (56%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	6 (7%)		7	1 (14%)	2 (29%)	4 (57%)	0
HEADACHE	≤63 Days (All)	191	34 (18%)	0.9661	48	10 (21%)	31 (65%)	5 (10%)	2 (4%)
	≤49 Days (Group 1)	29	5 (17%)		8	1 (13%)	6 (75%)	1 (13%)	0
	50-56 Days (Group 2)	73	14 (19%)		20	4 (20%)	13 (65%)	2 (10%)	1 (5%)
	57-63 Days (Group 3)	89	15 (17%)		20	5 (25%)	12 (60%)	2 (10%)	1 (5%)

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
INSOMNIA	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	129 (68%)	0.0171	284	114 (40%)	100 (35%)	69 (24%)	1 (<1%)
	≤49 Days (Group 1)	29	13 (45%)		24	9 (38%)	7 (29%)	8 (33%)	0
	50-56 Days (Group 2)	73	50 (68%)		99	46 (46%)	39 (39%)	14 (14%)	0
	57-63 Days (Group 3)	89	66 (74%)		161	59 (37%)	54 (34%)	47 (29%)	1 (<1%)
DIARRHEA	≤63 Days (All)	191	53 (28%)	0.1914	69	36 (52%)	25 (36%)	8 (12%)	0
	≤49 Days (Group 1)	29	5 (17%)		6	4 (67%)	1 (17%)	1 (17%)	0
	50-56 Days (Group 2)	73	18 (25%)		25	16 (64%)	7 (28%)	2 (8%)	0
	57-63 Days (Group 3)	89	30 (34%)		38	16 (42%)	17 (45%)	5 (13%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	**(cont.)**								
DYSPEPSIA	≤63 Days (All)	191	2 (1%)	1.0000	2	0	0	1 (50%)	1 (50%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	0	1 (100%)
FLATULENCE	≤63 Days (All)	191	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		2	0	1 (50%)	1 (50%)	0
NAUSEA	≤63 Days (All)	191	110 (58%)	0.1075	155	66 (43%)	50 (32%)	39 (25%)	0
	≤49 Days (Group 1)	29	13 (45%)		15	5 (33%)	6 (40%)	4 (27%)	0
	50-56 Days (Group 2)	73	39 (53%)		54	27 (50%)	21 (39%)	6 (11%)	0
	57-63 Days (Group 3)	89	58 (65%)		86	34 (40%)	23 (27%)	29 (34%)	0
VOMITING	≤63 Days (All)	191	40 (21%)	0.1042	56	12 (21%)	24 (43%)	20 (36%)	0
	≤49 Days (Group 1)	29	2 (7%)		3	0	0	3 (100%)	0
	50-56 Days (Group 2)	73	16 (22%)		19	3 (16%)	11 (58%)	5 (26%)	0
	57-63 Days (Group 3)	89	22 (25%)		34	9 (26%)	13 (38%)	12 (35%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS	**(cont.)**								
HYPERVENTILATION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	191	13 (7%)	0.0163	18	1 (6%)	8 (44%)	9 (50%)	0
	≤49 Days (Group 1)	29	1 (3%)		3	0	0	3 (100%)	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	11 (12%)		13	1 (8%)	6 (46%)	6 (46%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	**(cont.)**								
LEUKORRHOEA	≤63 Days (All)	191	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	191	10 (5%)	0.0069	14	0	6 (43%)	8 (57%)	0
	≤49 Days (Group 1)	29	1 (3%)		3	0	0	3 (100%)	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	9 (10%)		11	0	6 (55%)	5 (45%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
VAGINITIS	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	191	187 (98%)	0.0313	662	221 (33%)	243 (37%)	175 (26%)	23 (3%)
	≤49 Days (Group 1)	29	27 (93%)		93	27 (29%)	46 (49%)	20 (22%)	0
	50-56 Days (Group 2)	73	71 (97%)		258	98 (38%)	86 (33%)	64 (25%)	10 (4%)
	57-63 Days (Group 3)	89	89 (100%)		311	96 (31%)	111 (36%)	91 (29%)	13 (4%)

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	191	187 (98%)	0.0313	624	209 (33%)	230 (37%)	166 (27%)	19 (3%)
	≤49 Days (Group 1)	29	27 (93%)		89	26 (29%)	43 (48%)	20 (22%)	0
	50-56 Days (Group 2)	73	71 (97%)		239	90 (38%)	78 (33%)	61 (26%)	10 (4%)
	57-63 Days (Group 3)	89	89 (100%)		296	93 (31%)	109 (37%)	85 (29%)	9 (3%)
ASTHENIA	≤63 Days (All)	191	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
BACK PAIN	≤63 Days (All)	191	13 (7%)	1.0000	22	5 (23%)	9 (41%)	4 (18%)	4 (18%)
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	5 (7%)		11	4 (36%)	6 (55%)	1 (9%)	0
	57-63 Days (Group 3)	89	6 (7%)		9	0	2 (22%)	3 (33%)	4 (44%)
FATIGUE	≤63 Days (All)	191	4 (2%)	0.2093	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	29	2 (7%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
FEVER	≤63 Days (All)	191	2 (1%)	0.4261	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		3	3 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
HOT FLUSHES	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	191	4 (2%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		3	1 (33%)	0	2 (67%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: DEAN (#27)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS	**(cont.)**								
INFECTION VIRAL	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	115	110 (96%)	0.8419	513	160 (31%)	188 (37%)	165 (32%)	0
	≤49 Days (Group 1)	23	22 (96%)		84	30 (36%)	27 (32%)	27 (32%)	0
	50-56 Days (Group 2)	50	47 (94%)		220	59 (27%)	86 (39%)	75 (34%)	0
	57-63 Days (Group 3)	42	41 (98%)		209	71 (34%)	75 (36%)	63 (30%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
SKELETAL PAIN	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	19 (17%)	0.0277	26	8 (31%)	17 (65%)	1 (4%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	9 (18%)		14	3 (21%)	10 (71%)	1 (7%)	0
	57 63 Days (Group 3)	42	10 (24%)		12	5 (42%)	7 (58%)	0	0
DIZZINESS	≤63 Days (All)	115	4 (3%)	0.8288	5	3 (60%)	2 (40%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	1 (50%)	0	0
HEADACHE	≤63 Days (All)	115	17 (15%)	0.0388	21	5 (24%)	15 (71%)	1 (5%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	8 (16%)		11	1 (9%)	9 (82%)	1 (9%)	0
	57-63 Days (Group 3)	42	9 (21%)		10	4 (40%)	6 (60%)	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	115	3 (3%)	0.5960	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	2 (5%)		4	2 (50%)	2 (50%)	0	0
ANOREXIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
DEPRESSION	≤63 Days (All)	115	1 (<1%)	0.5652	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		3	1 (33%)	2 (67%)	0	0
DYSPAREUNIA	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	78 (68%)	0.2134	144	61 (42%)	55 (38%)	28 (19%)	0
	≤49 Days (Group 1)	23	12 (52%)		22	9 (41%)	7 (32%)	6 (27%)	0
	50-56 Days (Group 2)	50	36 (72%)		65	22 (34%)	31 (48%)	12 (18%)	0
	57-63 Days (Group 3)	42	30 (71%)		57	30 (53%)	17 (30%)	10 (18%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	**(cont.)**								
CONSTIPATION	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
DIARRHEA	≤63 Days (All)	115	42 (37%)	0.7693	48	27 (56%)	14 (29%)	7 (15%)	0
	≤49 Days (Group 1)	23	7 (30%)		9	4 (44%)	3 (33%)	2 (22%)	0
	50-56 Days (Group 2)	50	20 (40%)		23	10 (43%)	9 (39%)	4 (17%)	0
	57-63 Days (Group 3)	42	15 (36%)		16	13 (81%)	2 (13%)	1 (6%)	0
FLATULENCE	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	115	63 (55%)	0.4213	73	27 (37%)	29 (40%)	17 (23%)	0
	≤49 Days (Group 1)	23	10 (43%)		11	4 (36%)	4 (36%)	3 (27%)	0
	50-56 Days (Group 2)	50	30 (60%)		33	10 (30%)	15 (45%)	8 (24%)	0
	57-63 Days (Group 3)	42	23 (55%)		29	13 (45%)	10 (34%)	6 (21%)	0
VOMITING	≤63 Days (All)	115	19 (17%)	0.5801	21	5 (24%)	12 (57%)	4 (19%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	50	9 (18%)		9	2 (22%)	7 (78%)	0	0
	57-63 Days (Group 3)	42	8 (19%)		10	2 (20%)	5 (50%)	3 (30%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	2 (2%)	0.1699	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	1 (50%)	0	0
DYSURIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	115	10 (9%)	1.0000	12	3 (25%)	1 (8%)	8 (67%)	0
	≤49 Days (Group 1)	23	2 (9%)		3	1 (33%)	0	2 (67%)	0
	50-56 Days (Group 2)	50	4 (8%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	42	4 (10%)		5	1 (20%)	0	4 (80%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	**(cont.)**								
BREAST DISCHARGE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	115	1 (<1%)	0.2000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	115	7 (6%)	0.6803	8	0	1 (13%)	7 (88%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	50	2 (4%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	3 (7%)		4	0	0	4 (100%)	0
VAGINITIS	≤63 Days (All)	115	2 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	115	109 (95%)	0.5723	322	85 (26%)	110 (34%)	127 (39%)	0
	≤49 Days (Group 1)	23	22 (96%)		59	20 (34%)	20 (34%)	19 (32%)	0
	50-56 Days (Group 2)	50	46 (92%)		135	33 (24%)	43 (32%)	59 (44%)	0
	57-63 Days (Group 3)	42	41 (98%)		128	32 (25%)	47 (37%)	49 (38%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	115	109 (95%)	0.5723	303	76 (25%)	104 (34%)	123 (41%)	0
	≤49 Days (Group 1)	23	22 (96%)		57	19 (33%)	20 (35%)	18 (32%)	0
	50-56 Days (Group 2)	50	46 (92%)		129	30 (23%)	41 (32%)	58 (45%)	0
	57-63 Days (Group 3)	42	41 (98%)		117	27 (23%)	43 (37%)	47 (40%)	0
BACK PAIN	≤63 Days (All)	115	11 (10%)	0.0452	13	5 (38%)	5 (38%)	3 (23%)	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	8 (19%)		10	4 (40%)	4 (40%)	2 (20%)	0
CHEST PAIN	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	115	2 (2%)	0.3173	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
LEG PAIN	≤63 Days (All)	115	2 (2%)	0.6796	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: CREININ (#28)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	**(cont.)**								
RIGORS	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	83	75 (90%)	1.0000	223	46 (21%)	82 (37%)	95 (43%)	0
	≤49 Days (Group 1)	28	25 (89%)		69	13 (19%)	37 (54%)	19 (28%)	0
	50-56 Days (Group 2)	37	34 (92%)		106	22 (21%)	35 (33%)	49 (46%)	0
	57-63 Days (Group 3)	18	16 (89%)		48	11 (23%)	10 (21%)	27 (56%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	7 (8%)	0.3605	7	2 (29%)	4 (57%)	1 (14%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	37	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	18	3 (17%)		3	1 (33%)	1 (33%)	1 (33%)	0
DIZZINESS	≤63 Days (All)	83	4 (5%)	0.4250	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	2 (11%)		2	1 (50%)	1 (50%)	0	0
HEADACHE	≤63 Days (All)	83	3 (4%)	1.0000	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	28 (34%)	0.2500	57	5 (9%)	17 (30%)	35 (61%)	0
	≤49 Days (Group 1)	28	6 (21%)		11	0	4 (36%)	7 (64%)	0
	50-56 Days (Group 2)	37	15 (41%)		32	3 (9%)	12 (38%)	17 (53%)	0
	57-63 Days (Group 3)	18	7 (39%)		14	2 (14%)	1 (7%)	11 (79%)	0
DIARRHEA	≤63 Days (All)	83	12 (14%)	0.4010	12	2 (17%)	3 (25%)	7 (58%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	37	7 (19%)		7	1 (14%)	3 (43%)	3 (43%)	0
	57-63 Days (Group 3)	18	3 (17%)		3	1 (33%)	0	2 (67%)	0
DYSPEPSIA	≤63 Days (All)	83	1 (1%)	0.2169	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	83	21 (25%)	0.0692	23	2 (9%)	7 (30%)	14 (61%)	0
	≤49 Days (Group 1)	28	3 (11%)		4	0	1 (25%)	3 (75%)	0
	50-56 Days (Group 2)	37	13 (35%)		14	2 (14%)	5 (36%)	7 (50%)	0
	57-63 Days (Group 3)	18	5 (28%)		5	0	1 (20%)	4 (80%)	0
VOMITING	≤63 Days (All)	83	20 (24%)	0.6742	21	0	7 (33%)	14 (67%)	0
	≤49 Days (Group 1)	28	5 (18%)		5	0	3 (60%)	2 (40%)	0
	50-56 Days (Group 2)	37	10 (27%)		11	0	4 (36%)	7 (64%)	0
	57-63 Days (Group 3)	18	5 (28%)		5	0	0	5 (100%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
EPISTAXIS	≤63 Days (All)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	83	2 (2%)	0.6956	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	83	2 (2%)	0.6956	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	83	70 (84%)	0.5823	155	39 (25%)	60 (39%)	56 (36%)	0
	≤49 Days (Group 1)	28	25 (89%)		56	12 (21%)	32 (57%)	12 (21%)	0
	50-56 Days (Group 2)	37	31 (84%)		69	19 (28%)	20 (29%)	30 (43%)	0
	57-63 Days (Group 3)	18	14 (78%)		30	8 (27%)	8 (27%)	14 (47%)	0
ABDOMINAL PAIN	≤63 Days (All)	83	69 (83%)	0.8059	150	38 (25%)	56 (37%)	56 (37%)	0
	≤49 Days (Group 1)	28	24 (86%)		53	11 (21%)	30 (57%)	12 (23%)	0
	50-56 Days (Group 2)	37	31 (84%)		67	19 (28%)	18 (27%)	30 (45%)	0
	57-63 Days (Group 3)	18	14 (78%)		30	8 (27%)	8 (27%)	14 (47%)	0
BACK PAIN	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
FEVER	≤63 Days (All)	83	2 (2%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
MALAISE	≤63 Days (All)	83	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

J:\USA\166B\SASPGMS\apdxd\final\ade3.SAS 30NOV98:11:19

FINAL

Appendix D, Table 5c (Continued)
Adverse Events Possibly or Probably Related to Misoprostol [1] By Center
[Safety Evaluable Patients]

Center: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
INFECTION	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Tables 16 and 25

October 18, 2000

Confidential and Privileged
Via Hand Delivery

Division of Prescription Drug Compliance and Surveillance
Center for Drug Evaluation and Research/FDA
7520 Standish Place, Room — (HFD-333)
Rockville, Maryland 20855

Re: Drug Product Listing (Form FDA 2657) for Mifeprex Tablets™, 200 mg.

Dear

On behalf of Danco Laboratories LLC (Danco), enclosed herewith is the completed Drug Product Listing (FDA Form 2657) for Mifeprex™ Tablets, 200 mg. See Tab 1. As we discussed last week, the National Drug Code (NDC) number on the form is comprised of the five (5) digit labeler code (64875) previously issued to Danco by FDA, as well as a three (3) digit code for the product (001, as the first product) and a two (2) digit code for the package (03, for the three tablet) both of which were assigned by Danco consistent with FDA's Drug Registration and Listing Instruction Booklet. Thus, the NDC number, as it appears on the final packaging, is 64875-001-03.

Also enclosed is the Mifeprex™ product carton and blister package, along with a copy of the Danco-approved blister pack foil backer. We note that the enclosed product carton is identical, in all respects, to the carton that will be distributed commercially. Similarly, the blister package, in terms of its overall configuration and relationship to the product carton, also is identical to the blister package that will be distributed commercially. However, as we discussed last week, the content of the information on the foil backer of the enclosed blister pack is an earlier version that has since been revised based upon comments received from FDA during the review period. The revised information, as it will appear on the commercial blister pack, is presented in Tab 2.

Finally, we note that the final package insert currently is being printed, and will be available within the next several weeks. As we discussed last week, the text of the package insert, which previously was reviewed and approved by FDA, now is being reformatted so

that it can be accommodated on appropriately sized printing stock. As soon as Danco receives and approves the final package insert, we will provide you with a copy for your records.

Should you or your colleagues have any questions or comments regarding the contents of this letter, please contact me at [redacted].

Thank you for your prompt attention to this matter.

Very truly yours,

/S/

Enclosure

cc: [redacted] OCC, GCF-1
[redacted] anco Laboratories, LLC
[redacted], Danco Laboratories, LLC

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Form Approved: OMB No. 0910-0045. Expiration Date: April 30, 2001. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMANS SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DRUG PRODUCT LISTING
(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM: Danco Laboratories LLC

LABELING REVISON
CHANGE OF:
☐ RTE OF ADMIN ☐ INDICATION
☐ NAME / DOSE / STR / INGR
☐ OTHER *(Specify)*

FOR FDA USE — CONTROL NO. — RECORD ID

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME	NATIONAL DRUG CODE: LABELER	PRODUCT
01			MIFEPREX	0064	7500 1

FDA APPLICATION NO.	REPORT DATE: MO	DA	YR	TYPE	TYPES OF BUSINESS: OTHER *(Specify)*	PRODUCT TYPE	OTHER *(Specify)*	BIOD	LEGAL STATUS	SCHED	PROP	PRODUCT DISCONTINUED: OTHER *(Specify)*	BASIS OF CONCENTRATION: WHOLE NUMBERS	DECIMAL	UNIT
*200687	10	18	00	D		H			R				200		MG

DOSAGE FORM	ROUTES OF ADMINISTRATION: 1	2	3	OTH	PT
500*001					

SEC	S	U	SAMPLE	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
03				033		BLPK
03						
03						
03						
03						

INITIAL MARKETING DATE: MO	YEAR	MOST RECENT MARKETING DATE: MO	YEAR	DISCONTINUED DATE: MO	YEAR

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000, or both (FDA&C Act, Section 303).

SEC	S	U	TYPE	PT	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC.	FDA USE ONLY: INGREDIENT NO.	AMOUNT: WHOLE NUMBER	DECIMAL	UNIT
05			A		MIFEPRISTONE		200		TAB
05			I		SILICA ANHYDROUS COLLOIDAL		NS		
05			I		CORN STARCH		NS		
05			I		POVIDONE		NS		
05			I		CELLULOSE MICROCRYSTALLINE		NS		
05			I		MAGNESIUM STEARATE		NS		
05									
05									
05									
05									

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07								
07								
07								

FORM FDA 2657 (10/98) PEVIOUS EDITION IS OBSOLETE.

Created by Electronic Document Services/USDHHS. (301) 443-2434 EF

MIF 001239

#FD-205

Date: 10/11/00 11:44
From: [redacted]
Subject: RU-486
To: [redacted]

I solicited all documents relating to RU-486 from staff in the Division of Prescription Drug Compliance and Surveillance, HFD-330, Office of Compliance, CDER. Attached are copies of documents.

[redacted] HFD-330

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 30, 1993

Edward S. Kornreich, Esq.
Chair, Committee on Medicine and Law
The Association of the Bar
of the City of New York
42 West 44th Street
New York, New York 10036-6690

Dear Mr. Kornreich:

This is in response to your letter of May 24, 1993, to Dr. Kessler concerning President Clinton's January 22, 1993, memorandum which directed Secretary Shalala to assess initiatives to promote the testing, licensing, and manufacturing in the United States of RU-486 (mifepristone) and to direct the Food and Drug Administration (FDA) to reassess whether RU-486 qualifies for importation under FDA's personal use importation policy. Specifically, you requested information about the status of the latter.

In accordance with the President's January 22 memorandum, FDA is reassessing whether RU-486 might qualify for importation under FDA's personal use importation policy and whether the import alert should be rescinded. The Agency plans to make a recommendation on this issue this summer. The lawsuit to which you referred, Benten v. Kessler, remains pending in federal district court.

Please be assured that we, too, firmly believe in the principle that women should have equal access to justice. The protections of the Federal Food, Drug, and Cosmetic Act apply to all women and men in this country.

Dr. Kessler has stated that because abortion is legal in the United States, if RU-486 is a safe and effective alternative to surgical abortion, women in this country should have access to that drug. We have encouraged the manufacturer of RU-486 to submit a new drug application to FDA so that we can assess its safety and efficacy. In accordance with the President's January 22 memorandum, we have continued to assess initiatives concerning licensing, testing, and manufacturing of RU-486 in this country.

As you may be aware, the manufacturer of RU-486 has agreed to license the drug to the Population Council, a non-profit scientific and technical organization, for testing and distribution in the United States and to transfer the technology

L-KORNREICH/MP-RU-486
CHRON
DRUGS

MIF 001242

necessary for producing the drug. The Population Council has stated its intention to begin a clinical trial to test the drug in the United States and to move as soon as possible to submit a new drug application to the Agency.

Thank you for expressing your organization's views on these important issues.

Sincerely yours,

/S/

to the Commissioner

APPEARS THIS WAY
ON ORIGINAL

THE ASSOCIATION OF THE BAR
OF THE CITY OF NEW YORK
42 WEST 44TH STREET
NEW YORK, N.Y. 10036-6690

COMMITTEE ON MEDICINE AND LAW

EDWARD S. KORNREICH
CHAIR
1585 BROADWAY
NEW YORK, N.Y. 10036
(212) 969-3395
FAX # (212) 969-2900

PHILIP M. GASSEL
SECRETARY
250 PARK AVENUE
NEW YORK, N.Y. 10177
(212) 351-4761
FAX # (212) 661-0989

May 24, 1993

Honorable David A. Kessler
Commissioner of Food and Drugs (HF-1)
Food and Drug Administration
Room 14-71
5600 Fishers Lane
Rockville, MD 20857

Re: RU-486

Dear Dr. Kessler:

As chair of the Committee on Medicine and Law of the Association of the Bar of the City of New York, I write to request a report on the status of your agency's reconsideration of the Bush administration's prior decision to exclude the abortifacient prescription drug RU-486 from the FDA's exemption allowing individuals to import a three-months' supply of an unapproved new drug for a serious medical condition where the drug presents no significant health hazard.

As you know, President Clinton signed an executive order on January 22, 1993 directing the FDA to reconsider the decision not to allow RU-486 to qualify for the personal use exemption. We are not aware that this directive has been implemented to date.

Based on our committee's study of the underlying facts, we do not perceive a rational basis for the exclusion of RU-486 from this exemption (see the decision in Benton v. Kessler, No.

CV-92-3161 (E.D.N.Y., July 14, 1992)). Moreover, the exclusion appears unwarranted in light of the principle that women should have equal access to justice.

We look forward to hearing from you.

Sincerely yours,

Edward S. Kornreich

ESK/vp
cc: Honorable Donna E. Shalala
Honorable Daniel P. Moynihan
Honorable Edward M. Kennedy
Honorable Henry A. Waxman
Honorable John A. Dingell

APPEARS THIS WAY
ON ORIGINAL

C

April 1, 1992

[redacted]

Dear [redacted]

This replies to your letters to Dr. Kessler, Commissioner, Food and Drug Administration (FDA) concerning your complaint with RS61443 use in a clinical trial.

We regret any incident that may have occurred during the time you were part of the trial. Perhaps if we give you some background information about people taking part in clinical trials, you will have a better understanding of the part that the FDA plays in the drug approval process.

Basically, FDA wants to be sure that the welfare of participants in clinical studies will be protected and that the studies will be planned and carried out by qualified experts. Drug sponsors arrange with physicians and hospitals to actually conduct the studies.

Institutions engaged in research involving humans will generally have their own Institutional Review Boards (IRB's) to review work done on the premises or elsewhere by the staff of the institution. FDA's IRB and informed consent regulations ensure that research subjects are informed and willing participants and that their health and safety are not unnecessarily endangered. As you are aware, informed consent is obtained and documented from each subject or the subject's legal representative.

However, taking part in a research project does not waive the subjects legal right to privacy, because study records are confidential. For this reason, we are not in a position to disclose information on drug studies. Usually the names of individual subjects are not needed by FDA -- only results of the study.

As an additional comment, the prescribing and administering of medications by or on order of a physician is considered the practice of medicine which is a State, not a Federal, function. You may wish to contact the appropriate State licensing authority.

We have enclosed the booklet, "New Drug Development in the United States," which will provide more detailed information concerning the drug approval process.

We hope that this information has been responsive to your request.

Sincerely yours,

[redacted]

Consumer Safety Officer
CDER Executive Secretariat Staff (HFD-8)
Center for Drug Evaluation and Research

Enclosure
cc:
HFD-1:9202-0051
HF-43:9201751 pre;9200232
HFA-224
HFD-8/C
HFD-8: [redacted] :3/18/92
Init: [redacted] :3/30/92
Edit: [redacted] :3/23/92
F/T:wb:3/30/92
Log #:027-016-C2 and 043-022-C2

APPEARS THIS WAY
ON ORIGINAL

a

American Nurses Association

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Categories: Breast Implants, Cancer, Dietary Supplement, Family, Food Labeling, General, Nursing, Women

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Categories: General, Pharmacy

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Categories: Gen Fax, General

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Categories: Dietary Supplement, Family, Food Labeling, Gen Fax, General

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American Society of Consultant Pharmacists

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Categories: General, Pharmacy

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Web Page: http://www.ashp.com
Categories: General, Journal Editors

Association of Reproductive Health Professions

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Categories: Family, General, Women

Association of Women's Health, Obstetrical & Neonatal Nurses

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National Medical Association

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Categories: General

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Categories: Business, Women

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Bus 2: (202) 986-0375
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Oth Fax: (202) 775-7465
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TIM HUTCHINSON
ARKANSAS

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ARMED SERVICES
HEALTH, EDUCATION, LABOR, AND PENSIONS
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United States Senate

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October 4, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

I am writing to express my strong concerns regarding the Food and Drug Administration's recent approval of the drug Mifepristone, commonly known as RU-486. Knowing that the mission of the Food and Drug Administration is to protect the public health by ensuring drugs are safe and effective, I would appreciate your response to the following questions:

- A detailed report in the September 5 edition of the *Wall Street Journal*, based in part from leaked documents from Danco Laboratories, strongly suggests that the RU-486 abortion pill that American women will receive is being manufactured in China. Those documents showed payments from Danco to an unnamed facility in China that is known to be manufacturing the pill for consumption within China, according to the *Journal*. As I understand it, the FDA has not made public the identity of the manufacturer of the abortion pill, ostensibly because of concerns for the security of the manufacturer. I am not asking for the name of the manufacturer if in fact it is located in the United States. However, I do want to know, is the abortion pill being imported from China? Is the pill being imported from another foreign nation? If so, which nation? If your response does not provide an explicit answer, please cite the legal authority to withhold the information.

- Under the terms of the Food and Drug Administration's approval of Mifepristone, the drug will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe Mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding--or they must have made plans in advance to provide such care through others. How does the FDA intend to ensure that this drug is only distributed to the appropriate physicians?

- Would you please outline the licensure requirements and any other criteria developed by the Food and Drug Administration for physicians who intend to prescribe and administer Mifepristone?

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00-6123

- According to press reports, in early June the FDA sent Danco Laboratories a letter in which the FDA, based on its reviews of RU-486 going back to 1996, proposed a number of carefully crafted regulations regarding the distribution and use of RU-486. The regulations incorporated in the FDA announcement last week, however, were much weaker than what had originally been proposed. What was the basis for the FDA changing these regulations between June and September?

- Currently, the FDA requires that physicians report complications and compliance problems to the sponsor, and then Danco Laboratories will report those instances back to the FDA. Would you elaborate on this reporting requirement and how the FDA intends to ensure that complications and compliance problems are actually reported?

- On January 22, 1993, President Clinton directed Secretary of Health and Human Services Donna Shalala to review the personal use import ban against Mifepristone and to assess initiatives for the agency's promotion of testing, licensing, and manufacturing Mifepristone. To your knowledge, is there any precedent for such a directive and has President Clinton ever issued a similar one?

- To what extent did the Food and Drug Administration assist Roussel-Uclif, the original manufacturer of Mifepristone, and the Population Council, the subsequent patent holder for the drug, in locating a manufacturer and distributor of Mifepristone?

- The clinical evidence suggested that Mifepristone is 99.5 percent successful if used in the first 49 days of pregnancy. Has the FDA examined the side effects resulting from the use of Mifepristone during any time period beyond 49 days for both the pregnant woman and the unborn fetus?

Thank you for your immediate attention to the critical matter. Considering the limited time Congress has to examine this issue during the 106th Congress, I would ask that you provide your answers no later than close of business on Friday, October 6, 2000.

With kind regards,

Sincerely,

Tim Hutchinson
United States Senator

** TOTAL PAGE.03 **

FAX

James M. Jeffords, Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510

Telephone: (202) 224-6770
FAX: (202) 228-0411

Majority Health Staff

Date: 2 October 2000

To:

FAX #:

From: Dirksen Lehman

Page 1 of: 2

Message: Joint ltr to Senator Jeffords re. mifepristone, RU 486

Rec. by hand
9/29/00
12:15 PM

United States Senate

WASHINGTON, DC 20510
September 28, 2000

Honorable James Jeffords
Chairman
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Jim:

The Food and Drug Administration (FDA) announced this morning the approval of mifepristone, better known as RU-486. This drug is designed for the termination of early pregnancy. We share with you our concerns regarding FDA's approval process for mifepristone and the health and safety of the women who use it.

As Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP), we urge you to hold a hearing on this matter prior to the adjournment of the 106th Congress. The FDA has a statutory obligation to ensure that human drugs are safe and effective for their intended use. In that regard, the HELP Committee has a responsibility to the American people to guarantee that the FDA's drug approval process is consistent, scientifically sound and that the drugs it approves do not jeopardize human health and safety. Mifepristone should not be an exception to this standard.

We thank you for your immediate attention concerning this matter and look forward to your timely reply.

Sincerely,

Rec. by hand
9/29/00
12:15 PM

United States Senate

WASHINGTON, DC 20510
September 28, 2000

Honorable James Jeffords
Chairman
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Jim:

The Food and Drug Administration (FDA) announced this morning the approval of mifepristone, better known as RU-486. This drug is designed for the termination of early pregnancy. We share with you our concerns regarding FDA's approval process for mifepristone and the health and safety of the women who use it.

As Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP), we urge you to hold a hearing on this matter prior to the adjournment of the 106th Congress. The FDA has a statutory obligation to ensure that human drugs are safe and effective for their intended use. In that regard, the HELP Committee has a responsibility to the American people to guarantee that the FDA's drug approval process is consistent, scientifically sound and that the drugs it approves do not jeopardize human health and safety. Mifepristone should not be an exception to this standard.

We thank you for your immediate attention concerning this matter and look forward to your timely reply.

Sincerely,

T. Hutchinson

Sam Brownback

Mike DeWine

Michael B. Enzi

Orrin Hatch

Jeff Sessions

cc:

* * * * * * * CONGRESSIONAL * * * * * * *
* * * DOCUMENT/INFORMATION REQUEST * * *

Date: September 29, 2000

From: Jesse A. Helms
United States Senator

Subj: Concern about the approval of RU-486 and Danco deal with Communist China.

FOR YOUR INFORMATION

TO: Dr. Henney

From: [redacted]
Office of Legislation

Room No: [redacted]
Phone No: [redacted]

APPEARS THIS WAY
ON ORIGINAL

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From:	**Jesse Helms**	*OS#:*	**092120000120**
Organization:	**Senator - North Carolina**	*Date on Letter:*	**9/18/00**
City/State:	**Washington DC**	*Date Received:*	**9/21/00**
On Behalf Of:		*Type:*	**Congressional**

Subject: **Abortion Drug, RU-486. Concerns re September 5, 2000, Wall Street Journal article, 'Abortion Pill Venture Keeps the Shadows Awaiting Approval,' which was based, in part, on leaked internal documents from Danco Laboratories. Also concerned about Danco deal with Communist China.**

Assigned to:	**FDA**	*Dep.ES:*	**Vacant**
PC:	———	*Date Assigned:*	**9/22/00**
Action Required:	**Sec Sig**	*Date Reassigned:*	
		Reply Due Date:	**10/6/00**

Info Copies To: **ASL; ASMB; ASPA; ASPE; ——— ; DEP; ESS; NIH; OGC; OIA; OPHS; SAMHSA; SEC**

Interim (YIN): **No** *Date Interim Sent:*

Comments:

File Index: **PO-4-5** *CCC:* ———

APPEARS THIS WAY
ON ORIGINAL

00-5910

United States Senate

COMMITTEE ON FOREIGN RELATIONS

WASHINGTON, DC 20510-6225

September 18, 2000

The Honorable Donna E. Shalala
U.S. Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I don't know whether you saw the September 5 Wall Street Journal article ("Abortion-Pill Venture Keeps the Shadows Awaiting Approval") which was based, in part, on leaked internal documents from Danco Laboratories.

Danco Laboratories, by the way, has pending before the FDA a letter seeking approval to market the RU-486 abortion pill in the United States.

I understand that Danco made a deal with Communist China for the manufacture of the abortion pills to be sold in the United States, *if FDA approval is granted*. If this is correct it raises a number of troubling questions:

(1) Is the facility in China a state-owned facility?

(2) Does the facility operate in accord with internationally recognized standards regarding worker safety, or with coercive or slave labor?

(3) Does the management of the facility enforce the birth-quota system, which involves the monitoring of all female employees' menstrual cycles for unauthorized pregnancies – and if so, what threats or penalties are applied to a female employee of the facility who becomes pregnant without a permit? (For example, is she threatened with the loss of her position unless she submits to an abortion?)

(4) Are abortion-inducing drugs already produced by the factory utilized as

part of the nationwide birth-quota enforcement system, which has been well documented to rely heavily on many forms of coercion?

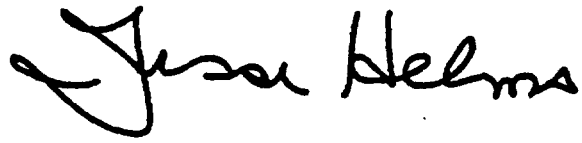
(5) Does the facility produce the anti-coagulation drugs that are reportedly given to some condemned prisoners prior to their execution, in order to facilitate immediate harvesting of their organs, which are sometimes provided to Party officials or to foreign buyers?

(6) Does the facility produce any drugs used in the interrogation of political prisoners?

I hope and pray that approval of RU-486 is not forthcoming. Surely, your Department will have to address these and other questions to be raised by many others if the Administration should make the mistake of approving the marketing of a Communist Chinese-manufactured abortion pill in the United States.

Sincerely,

JESSE HELMS:ggg



APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON FOREIGN RELATIONS

WASHINGTON, DC 20510–6225

September 18, 2000

The Honorable Donna E. Shalala
U.S. Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I don't know whether you saw the September 5 Wall Street Journal article ("Abortion-Pill Venture Keeps the Shadows Awaiting Approval") which was based, in part, on leaked internal documents from Danco Laboratories.

Danco Laboratories, by the way, has pending before the FDA a letter seeking approval to market the RU-486 abortion pill in the United States.

I understand that Danco made a deal with Communist China for the manufacture of the abortion pills to be sold in the United States, *if FDA approval is granted*. If this is correct it raises a number of troubling questions:

(1) Is the facility in China a state-owned facility?

(2) Does the facility operate in accord with internationally recognized standards regarding worker safety, or with coercive or slave labor?

(3) Does the management of the facility enforce the birth-quota system, which involves the monitoring of all female employees' menstrual cycles for unauthorized pregnancies – and if so, what threats or penalties are applied to a female employee of the facility who becomes pregnant without a permit? (For example, is she threatened with the loss of her position unless she submits to an abortion?)

(4) Are abortion-inducing drugs already produced by the factory utilized as

part of the nationwide birth-quota enforcement system, which has been well documented to rely heavily on many forms of coercion?

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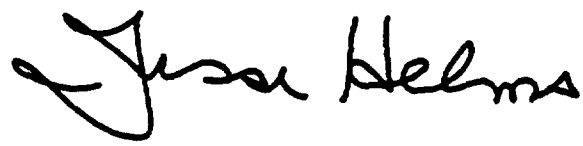
(6) Does the facility produce any drugs used in the interrogation of political prisoners?

I hope and pray that approval of RU-486 is not forthcoming. Surely, your Department will have to address these and other questions to be raised by many others if the Administration should make the mistake of approving the marketing of a Communist Chinese-manufactured abortion pill in the United States.

Sincerely,

JESSE HELMS:ggg



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ON ORIGINAL

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DATE: SEPTEMBER 28, 2000

FROM: [redacted] DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: CANCELLATION OF IMPORT ALERT #66-47, "AUTOMATIC DETENTION OF ABORTIFACIENT DRUGS"

TO: IMPORT PROGRAM MANAGERS

This alert has been cancelled. Districts may refer to Import Alert #66-41 for current guidance concerning the abortifacient product, mifepristone.

FOI: No purging required

PREPARED BY: DIOP, Operations & Policy Branch

DATE LOADED INTO FIARS: September 28, 2000

/s/

APPEARS THIS WAY
ON ORIGINAL

DATE: SEPTEMBER 28, 2000

FROM: [redacted] DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: REVISION OF THE ATTACHMENT TO IMPORT ALERT #66-41, "UNAPPROVED NEW DRUGS PROMOTED IN THE U.S."

TO: IMPORT PROGRAM MANAGERS

The following product has met the criteria for detention without physical examination:

PRODUCT/ PRODUCT CODE	SOURCE	COUNTRY
Mifepristone 65J[] [] [] []/ 65D[] [] [] []	All	All

FDA has determined that unapproved versions of mifepristone manufactured outside the U.S. are being promoted in this country for use to end pregnancy. Due to the risks to the safety of the user in inadequately controlled settings, mifepristone should be considered inappropriate for release under the Personal Import Guidance. Districts encountering entries of mifepristone should determine whether the importer of record for the article being entered is Danco Laboratories, LLC, New York, New York (distributor of the U.S. approved product) or whether the article is being entered under an IND that is in effect. In such circumstances (when the article is being imported by the distributor of the U.S. approved product or under an IND that is in effect), the article is outside the scope of this guidance.

(Districts should contact CDER for verification of IND status.)

Please add this product to the attachment for Import Alert #66-41.

RECOMMENDED BY: DIOP (HFC-170)

FOI: No purging required

PREPARED BY: DIOP, Operations & Policy Branch

DATE LOADED INTO FIARS: September 28, 2000

/s/

APPEARS THIS WAY ON ORIGINAL

DATE: SEPTEMBER 28, 2000

FROM: [redacted] DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: REVISION OF IMPORT ALERT #66-41, "UNAPPROVED NEW DRUGS PROMOTED IN THE U.S."

TO: IMPORT PROGRAM MANAGERS

NOTE: This revision updates the alert into the current format. Additional changes are bracketed by asterisks (***).

TYPE OF ALERT: ***Detention Without Physical Examination (DWPE)***

(Note: This import alert contains guidance to FDA field personnel only. It does not establish any requirements, or create any rights or obligations on FDA or on regulated entities.)

PRODUCT: Unapproved new drugs

PRODUCT CODE: ***See attachment***

PROBLEM: Unapproved drugs promoted in the U.S.

OASIS CHARGE CODE: UNAPPROVED

PAF: AAP (Approvals)

***PAC: 56008H
63001***

COUNTRY: All

MANUFACTURER/ SHIPPER: See attachment

REFERENCE: ***Regulatory Procedures Manual Chapter 9, Subchapter "Coverage of Personal Importations" issued 12/11/89. (Note: This subchapter, previously designated as RPM 9-71, was issued to consolidate guidance that previously existed in RPM Chapters: 9-71, "Mail Importations" and Chapter 9-72, "Coverage of Importations Contained in Personal Baggage," and the Pilot Guidance for Release of Mail Importation dated July 29, 1988.)***

Compliance Policy Guide (CPG) 120.500 (formerly 7150.10) gives extensive background on health fraud, and the indirect risks of relying on unproven remedies. Health fraud has been defined by the agency as the promotion of unproven medical products.

CHARGE: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an effective new drug application (NDA) [Unapproved New Drug, Section 505(a)".]

RECOMMENDING OFFICE: Division of Import Operations and Policy (HFC-170)

REASON FOR ALERT:

Media reports concerning FDA'S guidance for release of importations for personal use have inaccurately suggested that any unapproved drug may be imported through the mail for personal use. The pilot guidance and subsequent Regulatory Procedures Manual Subchapter, "Coverage of Personal Importations," that issued is much more restrictive than reported. The RPM subchapter provides guidance for use in those instances in which field personnel determine that the exercise of discretion regarding the admissibility of an unapproved drug might be appropriate. The guidance is by its very terms discretionary, and does not provide anyone with a right to import any drug.

The guidance provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, the drug is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and it is not considered to represent an unreasonable risk. The guidance is intended to apply only to: (1) persons who have received treatment in a foreign country with an unapproved drug which is not available in the United States, and who, upon returning to the United States, have imported the drug for their personal use in an effort to continue the treatment started abroad; and (2) persons who have made their own arrangements for obtaining an unapproved drug from foreign sources, when the drug has not been promoted in the United States.

When there is evidence of promotion of unapproved drugs to persons in the United States, the products should be considered for detention. Evidence of promotion may consist of soli-itations for mail orders, press releases, advertising materials, and other public announcements that are directed to persons residing in the U.S.

The subchapter of the RPM on coverage of personal importations provides guidance for FDA personnel on when it is appropriate to recommend import alerts involving unapproved products likely to be imported for personal use. Such recommendations are appropriate when an unapproved product represent a health fraud, as defined in CPG 120.500 or an unapproved foreign product is promoted for mail-order shipments. Thus, the field may recommend an import alert when an unapproved product poses either a direct health rick or indirect health risk.

GUIDANCE:

Districts may detain without physical examination any unapproved drug listed in the attachment.

Districts may also detain without physical examination any other unapproved drug that fails to meet the discretionary release criteria in the RPM. When detained products that appear to meet these criteria and are not listed in the attachment, districts should forward documentation to DIOP for consideration for inclusion in this alert.

SPECIAL NOTE:

Districts should continue to enforce, as appropriate, related import alerts restricting fraudulent, dangerous, and

commercial unapproved drug importations.

FOI: No purging required.

KEYWORDS: New drugs, unapproved new drugs

PREPARED BY: DIOP, Operations and Policy SDWG: HFC-172, _____
DATE LOADED
INTO FIARS: September 28, 2000

/s/

APPEARS THIS WAY
ON ORIGINAL

ATTACHMENT TO IMPORT ALERT #66-41

Unapproved new drugs that may be subject to DWPE

Note: The full attachment identifying the products that may be subject to this guidance was not reissued with the text revision of this alert.

BUC & BEARDSLEY
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006-5503
(202) 736-3600
(202) 736-3608 (fax)

FACSIMILE TRANSMISSION

September 27, 2000

Please deliver to: _____ _____ (f) _____ (t)

From: Nancy L. Buc (202) 736-3608 (f) (202) 736-3610 (t)
Sender's Direct Dial

Total Pages (including cover sheet): 2

COMMENT:

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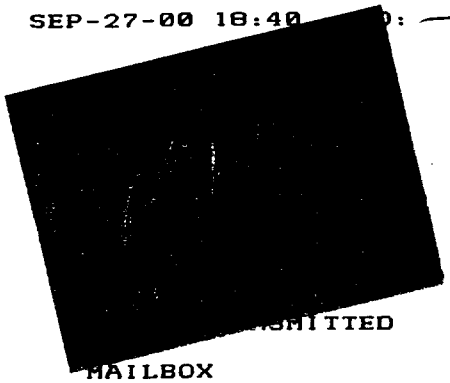
ON ORIGINAL

If you do not receive legible copies of all pages, please call (202) 736-3600.

××× TRANSMISSION REPORT ×××

SEP-27-00 18:40 [redacted] DDMAC



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SECURITY	OFF
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MACHINE ENGAGED	01'01
JOB NUMBER	898

THIS TRANSMISSION IS COMPLETED.

LAST SUCCESSFUL PAGE 003

BEST POSSIBLE COPY

9/27 9:30

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MIF 001275

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Date: 9/27/2000 11:52
From: [redacted]
Subject: France Experience
To: See Below

In today's session, one question was:

What percentage of abortions in France are medical, if overall the total numbers did not change?

The total number of abortions in France has remained stable at around 180,000 per year. Currently, about 33% of these are medical using mife and misoprostol.

When the above medical regimen was first approved, during that first year, about 10% of abortions were done medically and 90% were surgical.

[redacted]

To: [redacted] (OC)
To: [redacted]
To: [redacted] (FDADR)
To: [redacted] (OC)
CC: [redacted]
CC: [redacted]

APPEARS THIS WAY
ON ORIGINAL

Population Council

Sandra P. Arnold
Vice President
Corporate Affairs

September 27, 2000

[redacted]

Office of Drug Evaluation III
Division of Reproductive and
Urologic Drug Products (HFD-580)
Attention: Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-687 Mifepristone 200 mg Oral Tablets;
Amendment 067; Revisions to Package Insert and
Prescriber's Agreement/Order Form

Dear [redacted]

I am enclosing a revised package insert and a revised Prescriber's Agreement/Order Form. In accordance with telephone discussions today about training opportunities, we have deleted the penultimate paragraph (beginning [redacted], under DOSAGE AND ADMINISTRATION in the package insert, the last paragraph of text (beginning [redacted] .") in the Prescriber's Agreement, and the [redacted]

Sincerely,

Sandra P. Arnold /s/b

Sandra P. Arnold

APPEARS THIS WAY
ON ORIGINAL

One Dag Hammarskjold Plaza, New York, New York 10017
Telephone: (212) 339-0663 Facsimile: (212) 980-3710 Email: sarnold@popcouncil.org http://www.popcouncil.org

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF THE CENTER DIRECTOR
EXECUTIVE OPERATIONS STAFF
TELEPHONE NUMBER
FAX NUMBER

DATE: 9-26-00

TO:

TELEPHONE NUMBER:

FAX NUMBER:

FROM:

TELEPHONE NUMBER:

TOTAL NUMBER OF PAGES: 3 (Excluding Cover Sheet)

COMMENTS:

APPEARS THIS WAY
ON ORIGINAL

(Kaiser Family Foundation, National Survey of Views of Women's Health Care Provicders: An Update on Mifepristone, http://www.kff.org/content/2000/20000613a/Toplines.pdf.)

The government cannot treat abortion and abortificients differently than comparable procedures and drugs without a compelling reason for doing so (Greenville Women's Clinic v. Bryant, 66 G. Supp. 2d 691 (D.S.C. 1999), appeal argued, No. 99-1319 (4th Cir. Jan 27, 2000).

The Supreme Court has long recognized that the exercise of medical judgment by a licensed physician is sufficient to ensure that an abortion is safely performed, and that any additional barriers beyond licensure of the woman's physician are therefore improper obstacles to a woman's exercise of her right to privacy (Doe v. Bolton, 410 U.S. 179, 197-200 (1973)). Any special requirements imposed on physicians who prescribe mefepristione – like certification in ultrasonography use of possession of hospital admitting privileges – would impermissibly interfere with this zone of protected medical judgment.

American Medical Women's Association: copy of their Journal issue on Medical Abortions. They find no medical rationale for encumbering distribution.

Against restrictions, and concerned about unwarranted implications for limitations. Will other drugs, such as those used in chemotherapy and ulcer treatment that have the possible side effect of inducing abortions, be similarly regulated?

Effect on Other Uses

Since mifepristone has anti-glucocorticoid action, it may point to new treatments for such diseases as depression, Alzheimer's, and other conditions related to elevated cortisol levels. It has been found to be an effective treatment for Cushing's Syndrome.

Mifepristone has uses in treating other conditions, such as Parkinson's disease. Will all its uses require the same restrictions?

RU496 used in conjunction with tamoxifen improves the chance for long-term survival.

It seems to me that for a drug which has shown signs of aiding in the fight against ovarian cancer, fibroid tumors, meningoma, and endometriosis to be held hostage to social conventions is outside the role of the FDA.

Mifepristone shows promise as a possible treatment for ovarian cancer, endometriosis, fibroid tumors, meningioma, and some types of breast cancer, and in assisting labor induction.

Preliminary results of mifepristone for treating fibroid tumors suggest it is quite effective at relieving symptoms and reducing tumor size by 50 percent.

This proposed restriction is a source of concern for brain tumor advocates like the North American Brain Tumor Coalition. FDA's proposed course of action will mean that these patients will continue to be deprived of access to mifepristone. FDA authority does not extend to practice of medicine. Once a drug has been approved, physicians may prescribe it for other uses, based on medical judgment. This practice is of critical importance in oncology, where FDA approvals of new indications cannot match the pace of scientific progress.

Against Registry

Many indicate concern that a registry of physicians would provide a target for terrorism.

Against Follow-Up Study

As far as a required follow up study – that is a gross violation of the privacy rights of women and confidentiality with their doctors. If anything, it should be voluntary.

Safety Concerns

An Iowa woman participating in the U.S. trials in 1994 nearly bled to death. In addition, nausea, diarrhea, vomiting, and painful cramping are quite often side effects. Also infection and heart palpitations. Unknown long-term effects. Impact on future pregnancies.

APPEARS THIS WAY
ON ORIGINAL

FAX COVER SHEET

DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATIONS
CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

Date: September 26, 2000

To: Nancy L. Buc
Buc & Beardsley
919 Eighteenth Street, NW
Suite 600
Washington, DC 20006-5503

Phone: 202-736-3610 **Fax:** 202-736-3608

From: [redacted]

No. of Pages without coversheet: 4

Phone: [redacted] (Surveillance and Enforcement)

Fax: [redacted]

[redacted]

NANCY L. BUC
BUC & BEARDSLEY
202-736-3610

9/26/00

Dear _____

10 copies will be delivered tomorrow, ~~#~~ the original certification signed by Ms. Arnold.

Nancy L. Buc

Population Council

Sandra P. Arnold
Vice President
Corporate Affairs

September 26, 2000

Office of Drug Evaluation III
Division of Reproductive and
Urologic Drug Products (HFD-580)
Attention: Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-687, Mifepristone 200 mg. Oral Tablets;
Amendment 067; Post-approval Commitments; Debarment Certification

Dear

We agree to submit the protocols for the Phase IV studies within 6 months of approval of this NDA. I am attaching an updated debarment certification statement.

Sincerely,

Sandra P. Arnold

Sandra P. Arnold

APPEARS THIS WAY
ON ORIGINAL

One Dag Hammarskjold Plaza, New York, New York 10017
Telephone: (212) 339-0663 Facsimile: (212) 980-3710 Email: sarnold@popcouncil.org http://www.popcouncil.org

Mifepristone
NDA No. 20-687

GENERIC DRUG ENFORCEMENT ACT OF 1992
CERTIFICATION STATEMENT

The Population Council hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Signed: Sandra Arnold Date: 9/26/00

SANDRA ARNOLD, VICE PRESIDENT

The Population Council

APPEARS THIS WAY
ON ORIGINAL

Population Council

Sandra P. Arnold
Vice President
Corporate Affairs

ORIGINAL

September 26, 2000

Office of Drug Evaluation III
Division of Reproductive and
Urologic Drug Products (HFD-580)
Attention: Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

ORIG AMENDMENT

BC

Re: NDA 20-687, Mifepristone 200 mg Oral Tablets;
Amendment 066; Revision to Package Insert

Dear

I am enclosing a revised package insert. In accordance with telephone discussions on September 25, it revises the second sentence under Table 2 so that " . . " is replaced by " . . .have been reported after exposure during the first trimester."

Sincerely,

Sandra P. Arnold

Sandra P. Arnold

APPEARS THIS WAY
ON ORIGINAL

Facsimile: (212) 980-3710
One Dag Hammarskjold Plaza, New York, New York 10017
Email: sarnold@popcouncil.org http://www.popcouncil.org

ROUTING SLIP
GENERATED BY: HFW-1
DATE: SEP 25, 2000

FDA CONTROL NUMBER: 00 5922 TRACER #: OS #:

DATE OF CORRESPONDENCE: 09/25/00 DATE INTO FDA: 09/25/00

TO: JANE E HENNEY HF-1

FROM: THOMAS J BLILEY, HOUSE, COMMITTEE ON COMMERCE

SYNOPSIS: CMTE WANTS ALL INFORMATION RELATING TO THE DRUG MASTER FILE AND INSPECTION REPORTS CONCERNING [redacted] SHANGHAI HUALIAN PHARMACEUTICAL CO.

LEAD OFFICE: HFW-1 HOME OFFICE: HFW-1

CONTACT/PHONE#: [redacted]

COPIES: HFW-1 [redacted]
HFW-1 [redacted]
HFW-1 [redacted]
HFW-1 [redacted]

COORDINATION:

SIGNATURE REQUIRED: ASSOCIATE COMMISSIONER FOR LEGISLATION

REFERRALS FROM HFW-1

ASSIGNED TO	ACTION	DUE DATE
HFW-1 [redacted]	PREPARE DIRECT REPLY	09/27/00

REMARKS: CMTE WANT INFORMATION FOR PREPARATION OF THE 10/3/00. IF QUESTIONS CONTACT ALAN SLOBODIN AT 202-225-2927.

APPEARS THIS WAY
ON ORIGINAL

PUBLIC ADVOCATE FOR THE CITY OF NEW YORK

MARK GREEN
Public Advocate

September 22, 2000

Jane Henney, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: RU-486

Dear Dr. Henney:

Earlier this week Planned Parenthood of New York City, NARAL-New York, the Access Project and Physicians for Reproductive Health and Choice joined me in convening a public hearing in New York City on pending action by the Food and Drug Administration on mifepristone, also known as RU-486.

Allowing New York women access to this safe and effective drug has been a priority of mine for a nearly a decade. As NYC Consumer Affairs Commissioner in the early 1990s, I worked closely with then Mayor David N. Dinkins to bring RU-486 to the United States. We convened roundtable discussions with reproductive and medical experts and religious leaders. We created a coalition of two dozen pro-choice mayors from around the country who together urged the president of the French company that controlled the patent on the drug to allow it to be exported here for testing. The coalition also wrote to then President George Bush urging him to take the drug off the import black list. We were unsuccessful until the first month of President Clinton's presidency, when he persuaded the French manufacturer to transfer its patent so clinical trials in the U.S. could begin.

So I was pleased this summer to hear that this non-surgical option might soon be available to American women considering having an abortion – and also concerned about the restrictions on access to RU-486 that the FDA is said to be considering. We called the hearing to explore whether these restrictions were medically necessary and whether they would have unintended effects that could hurt rather than help women. We heard

1 CENTRE STREET NEW YORK, NY 10007 TEL: (212) 669-7200 FAX: (212) 669-4701
mgreen@pubadvocate.nyc.gov TTY: (212) 669-7438

that the restrictions are not necessary, go far beyond the restrictions that apply to other drugs, and seriously undercut the main benefits of RU-486: wide accessibility of abortion and privacy.

As you approach the deadline for final action, I hope you will consider the enclosed summary and full testimony from our hearing on RU-486. I am pleased to submit it on behalf of the hearing panel made up of Jo Ivey Boufford, M.D., Dean of the Robert F. Wagner School of Public Service at New York University; Allan Rosenfield, M.D., Dean of the Mailman School of Public Health at Columbia University; Victor W. Sidel, M..D., President of the Public Health Association of New York City; and me.

Given that the FDA deemed RU-486 "safe and effective" four years ago and it has been used widely abroad, it is past time for the FDA to approve RU-486. RU-486 should be treated like any other drug. Once it's approved for use, any physician should be able to prescribe it when he or she judges it medically appropriate. Afterall, doctors are not required to be heart surgeons in order to prescribe cholesterol-reducing medication.

RU-486 can help put reproductive choice where it belongs – in the hands of women and their doctors. Please do not allow ideology to supplant science.

Sincerely,

Mark Green

cc: Donna E. Shalala
Sarah Kovner

APPEARS THIS WAY
ON ORIGINAL

Public Hearing Summary:

The Impact of Possible FDA Restrictions On the Distribution and Use of RU-486

Convened by Mark Green Public Advocate for New York City

September 19, 2000
City Hall, New York City

Introduction

On September 19, 2000, New York City Public Advocate Mark Green convened a public hearing on the current status and future of the abortion pill mifepristone, more commonly known as RU-486.

Press and other reports suggest that RU-486 is on the verge of approval for use in the United States with potentially onerous, unprecedented restrictions imposed on its availability. The hearing was called to allow the leading medical and legal experts in the City and State of New York to go on the record regarding the safety, efficacy and availability of RU-486.

The testimony from the hearing demonstrates that: RU-486 is safe and effective; the need for RU-486 has not diminished since a decade ago when public health officials and abortion providers began trying to secure its approval and marketing rights in the U.S; a variety of health care professionals are qualified to provide medical abortion; and

increased anti-abortion activity and clinic violence make this not just a safe and early option for women, but vital to ensuring women's constitutional right to abortion.

Twelve medical and legal experts testified before a hearing panel made up of NYC Public Advocate Mark Green; Jo Ivey Boufford, M.D., Dean of the Robert F. Wagner Graduate School of Public Service at New York University; Allan Rosenfield, M.D., Dean of the Mailman School of Public Health at Columbia University; and Victor Sidel, M.D. Distinguished University Professor of Social Medicine at Montefiore Medical Center and Albert Einstein College of Medicine and President of the Public Health Association of New York City.

This document summarizes the testimony presented at the hearing.

Safety Issues: the Safety and Efficacy of RU-486

Eric Schaff, M.D., University of Rochester's Mifepristone Trials

Linda Prine, M.D., Family Practitioner and Planned Parenthood Abortion Provider

Carolyn Westhoff, M.D., Columbia College of Physicians and Surgeons, and the Mailman School of Public Health

Laura MacIsaac, M.D., Albert Einstein College of Medicine

The medical experts on the panel testified that there is vast and compelling evidence that RU-486 is both safe and effective as an abortifacient and that New York women who have used mifepristone are very satisfied with the experience and results. In addition to the half a million European women who have used the drug, rigorous clinical trials have been conducted in the U.S. These trials led the FDA to pronounce mifepristone safe and effective in March of 1996 and again in February of 2000.

Dr. Eric Schaff testified that since 1996 he has participated in six multi-center U.S. clinical trials of the mifepristone-misoprostal drug combination to terminate the pregnancies of more than 6,600 women. The trials found the two-drug intervention to be effective approximately 95% of the time when administered early in the pregnancy. Over 90% of the women in the trials found the procedure acceptable and would choose this method again if they were pregnant. Side effects from the drugs were common, but were acceptable to women.

New York women's experience tracks national statistics: 96% of women who were part of the U.S. clinical trials said they would recommend it to others and more than 90% said they would choose it again if necessary (Archives of Family Medicine, 1998).

Dr. Linda Prine addressed the proposed FDA restriction that would require that only doctors trained to perform surgical abortions be allowed to provide medical abortions for reasons of "safety." Dr. Prine is a family physician and also a surgical

abortion provider at Planned Parenthood of New York City, and spoke from experience. Family practitioners often initiate treatment for patients who in the end may need more specialized care. For example, a family physician may prescribe medication for a patient with heart pain. If more extensive treatment, such as surgery is needed later, the family practitioner refers the patient to a cardiac surgeon. Family practitioners deliver babies but may not be trained to perform caesarean sections; if a caesarian is necessary, the doctor would make a referral to an obstetrician/gynecologist. Knowing when to refer a patient to a specialist is a standard part of a family practitioner's medical training and routine. Medical abortion would be no different. Said Dr. Prine: "If the proposed requirement that medical abortion providers be trained in surgical abortion were applied to other areas of medicine, a primary care doctor would not be able to treat a patient for heart pain with medication or deliver a baby."

Dr. Carolyn Westhoff, Medical Director of New York Presbyterian Hospitals family planning and abortion services , has worked closely with Dr. Schaff throughout the clinical trials and agreed with his testimony. She rarely encounters emergencies with either medical or surgical abortion patients and believes that the rate of complications is very similar with either method of abortion. An additional study at her clinic of patient satisfaction with both surgical and medical abortion investigated how patients felt physically, emotionally and psychologically both before they underwent the abortion and several weeks to a month following. The results were similar for both abortion techniques. Medical and surgical abortion patients showed equal improvement immediately after and a month after abortions. "Therefore", said Dr. Westhoff, "I think

it is very important that we should all accept mifepristone as a great option for women to have as soon as possible."

Dr. Laura MacIsaac, an obstetrician/gynecologist in private practice, director of family planning and abortion services at Albert Einstein College of Medicine and former medical director at Planned Parenthood of New York City, gave her perspective as a busy clinician performing the full range of obstetrician/gynecologist services but being particularly well educated and skilled in the provision of abortion services.

One of Dr. MacIsaac's main concerns is that if the restrictions on mifepristone become unwieldy the entire benefit of giving her female patients the chance to make abortion choices early will be removed, at the risk of patient safety. The longer a woman waits to obtain an abortion, the higher the morbidity associated with the procedure. Dr. MacIsaac concluded: "The availability of mifepristone will change the whole dialogue about fertility awareness for the general obstetrician/gynecologist physician and her patients by encouraging women to make their pregnancy decisions early and by that virtue in itself, far safer than anything we do now."

Access Issues: Scientific Evidence Regarding Restrictions on Early Non-Surgical Abortion

Lawrence Lader, Abortion Rights Mobilization

Joan Malin, Planned Parenthood of New York City, Inc.

Steven Tamarin, M.D., Physicians for Reproductive Choice and Health

Virginia Reath, R.P.A., M.P.H., Access Project

Women need greater access to abortion services. The shortage of abortion providers nationwide and the marginalization of abortion *outside* the scope of women's basic health care needs have had a dramatic impact on the health and well-being of women and their families. Mifepristone has the potential to expand access to abortion by giving women another medical option. Because mifepristone can induce abortion without surgery, it can be provided in almost any health care setting, and it can be safely administered not only by obstetrician/gynecologist but also by family doctors and mid-level providers like physician's assistants and nurse practitioners. If mifepristone is approved with appropriate safeguards and without unnecessary restrictions, it will have a profound impact on women's lives by expanding *who* provides abortion services and *where*.

Joan Malin, president of Planned Parenthood of New York City, testified that based on inquires about PPNYC's training programs for RU-486 providers, medical professionals want to be able to offer the medical abortion option. This reflects national trends: A recent survey by the Kaiser Family Foundation (June 2000) found that about one third of gynecologists and family practice physicians who don't provide surgical abortions said they would be "likely" to prescribe mifepristone to their patients who

request it. This would significantly increase the availability of abortions -- especially early abortions.

In addition, restricting RU-486 administration privileges to physicians – and only physicians who perform surgical abortions would eliminate the opportunity for greater access to early abortion.

Planned Parenthood of New York City, Inc. believes that physician's assistants, nurse practitioners and other mid-level providers have the skills and clinical training needed to prescribe RU-486. Planned Parenthood has found that patient counseling is the most important skill that a clinician must have to administer medical abortion safely and effectively. Providers must be able to clearly communicate to women how to be participants in the process. Women need to know how and when the medications work, possible side effects, how to manage them, and when to seek follow-up care. These patient counseling skills and all other competencies needed to administer mifepristone effectively are skills that physician's assistants, nurse practitioners and other mid-level providers use in other aspects of their work and are well within their scope of practice.

Second, requiring that physicians who provide mifepristone be trained in surgical abortion is also a significant problem. Although providers of medical abortion must have surgical back-up arrangements, there is absolutely no reason for them to have surgical abortion experience, any more than there is reason for physicians prescribing ulcer medication to have training in gastric surgery.

In addition, requiring that the provider of mifepristone-induced abortion practice medicine more autonomously than other medical providers represents an unprecedented intrusion on medical practice in the absence of any clinical evidence that such restrictions are needed. Dr. Steve Tamarin, Board Member of Physicians for Reproductive Choice and Health, pointed out that this proposed restriction appears to require the establishment of new mechanisms for certification of providers of surgical abortion that are not justified for a procedure that is both one of the most common and one of the safest in medicine.

Lawrence Lader, president of Abortion Rights Mobilization (ARM), touched on the additional conditions for which RU-486 may be useful for treatment. In addition to the clinical trials of RU-486 that ARM oversees and that Dr. Schaff reported on earlier in the hearing, an ARM research project uses RU-486 to treat fibroid tumors, which are a major medical problem for women. The early results of these tests are highly encouraging. But it is difficult to test the use of RU-486 in treating fibroids, cancer and other conditions with the drug still awaiting approval.

"So long as mifepristone can be offered in the privacy of a doctor's office or the anonymity of a primary care clinic (where there are generally no protesters), the pool of potential providers is huge. However, if the FDA enacts the surgical-only and physician-only restrictions, this potential pool of providers would disappear," testified Joan Malin of PPNYC. "Medical abortion with mifepristone would be no more accessible than surgical abortion is now. For women living in the 42% of New York counties with no abortion provider, that would be very disappointing news."

Legal and Policy Issues: The Integrity of the Regulatory Process and the Importance of Precedent

Simon Heller, Center for Reproductive Law and Policy

Donna Lieberman, NYCLU Reproductive Rights Project

Kelli Conlin, National Abortion and Reproductive Rights Action League-NY

Nancy Millar, National Organization for Women

Placing inappropriate restrictions that are not medically called for on the delivery system for RU-486 would conflict with the *Roe v. Wade* Supreme Court decision establishing women's right to abortion, the governing language of the Food and Drug Administration and the laws of the State of New York.

According to Simon Heller, a lawyer with the Center for Reproductive Law and Policy, without compelling evidence to justify restrictions on physicians beyond thorough training and licensure, additional barriers and restrictions to abortion place improper obstacles to a woman's ability to exercise her right to privacy and a safe abortion. Said Mr. Heller:

> Access to abortifacients is cloaked with strong constitutional protection under the rights to privacy and equal protection of the laws. Accordingly,

the government and the FDA cannot impose restrictions on abortion access unless those restrictions further governmental interests in maternal health or potential life. Rather they threaten the health of women seeking abortions by greatly decreasing, if not entirely eliminating the increase in, the availability of abortion providers that would attend the approval of mifepristone without distribution restrictions.

Donna Lieberman, Director of the New York Civil Liberties Union's Reproductive Rights Project, pointed out that the FDA itself has said, "Congress did not intend the [FDA] to interfere with medical practice . . . [or] to regulate the practice of medicine as between the physician and the patient." (Quoted in *FTC v. Simeon Management Corp.*) A restriction that imposes special training and experiential requirements on medical professionals who seek to prescribe mifepristone, in essence, regulates the practice of medicine. Regulation of the practice of medicine is a matter for the states. Nothing in the FDA's authorizing statute empowers the agency to impose such restrictions. To the contrary, it is well established that "the FDA does not have jurisdiction to regulate the administration of a drug by a physician." (Quoted in *Simeon*) Indeed, the FDA itself recognizes that "the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert," without obtaining FDA approval. (Quoted in *Simeon*)

Furthermore, testified Ms. Lieberman, New York, like every other state, has its

own legislation that governs who can practice medicine and to what extent. In order to combat a healthcare provider shortage, New York approved certain clinical roles for Physician Assistants, Nurse Midwives, and Nurse Practitioners. These advanced healthcare practitioners have extensive medical training and wide-ranging scopes of practice that depend largely on their practice agreements with supervising or collaborating physicians. In addition, they are authorized to prescribe and dispense a broad range of medicine under New York law. She said: "The FDA does not have the authority to regulate RU-486 in a manner that would impinge on the ability of Physician Assistants, Nurse Midwives and Nurse Practitioners to serve their patients under the authority granted to them by the State."

A representative of the National Abortion and Reproductive Rights Action League - New York recapped RU-486's politically difficult road to approval in the U.S. and concluded by pointing out that the FDA is a government agency charged with neutrality, responsible for making decisions based on need, safety and efficacy, not popular opinion, emotion or organized pressure. "However, if one reviews the long, fraught journey of mifepristone through the FDA, it becomes clear that the main character of this story is not reason but politics," said a representative speaking for Kelli Conlin, president of NARAL-NY.

In the discussion it was noted the experience with RU-486 in other countries, which do not have the onerous restrictions proposed by the FDA indicates that these restrictions are not needed for the safe and effective use of RU-486.