

**Defendant's 2<sup>nd</sup> Abbreviated New Sample Vaughn Index**

**Including**

**FDA-Generated Documents Concerning Xenotransplantation Clinical Trials in General  
and**

**FDA-Generated Documents Contained in the IND "G" File or Relating to IND "G"**

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
201	General: Internal Memo re: Effects of Xenotransplantation in Humans. Comments by author are draft in nature.	2	pgs. 1-2: releasable with b(5) redactions	Amy Patterson, James Kaiser	Carolyn Wilson	09/10/97	DPP	5 USC 552(b)(5)
773	IND G: The document contains pharm / tox comments. The document contains questions to ask the sponsor to establish the validity and scientific merit of the toxicity study. The document also contains a description of a non-hold issue.  CCI: IND number, name of the clinical study.	2	pgs. 1-2: b(5) with sponsor info b(4) throughout entire document	Unknown	Unknown	01/10/95	CCI, DPP	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
775	Document Released in Entirety	8	None	Unknown	Amy Patterson	Unknown	None	
1088	General: Internal Email re: Life long xenotransplantation requirements if sponsor withdraws from IND. Non-responsive sponsor name and IND number. (i.e. not a porcine or non-human primate xenotransplantation sponsor)	2	pgs. 1-2: releasable with b(5) and non-responsive redactions	Phillip Noguchi	Thomas Eggerman	09/28/99	DPP, Non-responsive	5 USC 552(b)(5)

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1357	IND G: Internal Memo re: Holds For Lack of Assays. The memo addresses a numbered regulation in relation to a clinical hold. The memo discusses a numbered regulation in relation to an assay.	1	pg. 1: releasable with b(5) redactions	Amy Patterson	Bette Goldman	06/10/97	DPP	5 USC 552(b)(5)
1364	General: Internal Memos from various sources and various dates re: draft comments on solutions to problems regarding PERV Screening and an interpretation of data on PERV	2	pgs. 1-2: releasable with b(5) redactions	Tina Moulton	Amy Patterson	10/16/97	DPP	5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
1863	General: Internal Email re: Revised Questionnaire for Council of Europe. Email discussion on what Regulations and Laws apply to xenotransplantation in order to answer a Council of Europe questionnaire.	2	pgs. 1-2; releasable with b(5) redactions	Joseph A. Foster	Eda Bloom	02/01/00	DPP	5 USC 552(b)(5)
1913	General: Memo re: detection of eperythrozoon. The memos provides comments on porcine eperythrozoon.	1	pg. 1: b(5)	Amy Patterson	Philip Snoy	04/10/95	DPP	5 USC 552(b)(5)

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2001	Document Released In Entirely	2	pgs. 1-2: releasable	Unknown	Unknown	Undated	None	
2007	Document Released In Entirely	1	pg. 1:releasable	Unknown	Unknown	Undated	None	

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2093	General: Internal Memo that discusses steps to inactivate a virus.	1	pg. 1: releasable with b(5) redactions	Robin Biswas	Carolyn A. Wilson	04/07/95	DPP	5 USC 552(b)(5)
2280	General: Internal Memo contains a USDA contact for xenotransplantation issues. The memo discusses the importation of transgenic animals from the UK to set up breeding facilities. Memo discusses non-responsive sponsors and responsive sponsors. Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request.  CCI: The memo contains the name of the sponsor and a brief description of experiments.	4	pgs. 1-4: non-responsive, b(4), and b(5).	Thomas Eggerman	Steven Bauer	05/14/97	Non-Responsive, DPP, CCI	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)

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2390	Document Released in Entirely	2	pgs. 1-2:releasable	Unknown	Unknown	Undated	None	
2610	General: Internal email Exchange re: Laws applying to the use of animals in xenotransplantation. The non-responsive portions are non-FDA generated.	2	pgs. 1-2: releasable with b(5) and non-responsive redactions	Eda Bloom, R. Riseberg	Robert Lanman	01/28/00	DPP, Non-responsive	5 USC 552(b)(5)

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2713	General: Internal email Exchange re: Discussion of PERV infected animals and related data. Second email is non-responsive; not-FDA generated about PERV infected animals. Attached is a non-responsive, not FDA-generated document titled, "Experimental Cross Species Transmission of Porcine Endogenous Retrovirus to Guinea Pigs."	5	pgs. 1 1st email; releasable; rest of page: non-responsive; pgs. 2-5: non-responsive	Eda Bloom	Carolyn Wilson	01/06/00	Non-Responsive, DPP	5 USC 552(b)(5)
2762	General: Internal Chart re: Xenotransplantation clinical trials. Chart contains non-responsive sponsors and responsive sponsor information, product and clinical indications, clinical trial statuses, outcomes, and comments Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request.  CCI: names of sponsors; cells studied; diseases studied; clinical trial; IND numbers; number of patients; types of side effects; survival rates of patients	3	pgs. 1-3 releasable with b(4) and b(5) redactions	Unknown	Unknown	06/30/97	DPP, CCI	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
2783	Document Released in Entirely	1	pg. 1: releasable	Eda Bloom, Phillip Noguchi, Jay Siegel	Andrew Dayton	03/01/00	None	
3006	Document Released in Entirely	3 (originally stated as 1 page)	pgs. 1-3: releasable	Unknown	Amy Patterson	08/26/94	None	

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
3016	Document Released in Entirely	6	pgs. 1-6: releasable	Sponsor	Sharon Risso	10/27/94	None	
3024	General: Document on a clinical trial re: Xenogeneic cells for implantation in patients	5	pgs. 1-5; b(5)	Unknown	Sponsor	Undated	DPP	5 USC 552(b)(5)

Doc #	Description	Total Page	Pages Withheld	To:	From:	Date:	Reasons For Withholding	Statutory Authority
3098	IND G: Internal Email Exchange re: Species and strains for xeno database. The non-responsive pages discuss non-responsive sponsors. Non-responsive because the sponsor's IND is not responsive to the narrowed FOIA request.  CCI: Non-IND G sponsor names	40 (originally stated as 15 pages)	pgs. 3-7: releasable with b(5) and non-responsive redactions; pgs. 1-2, 8-40: non-responsive	Thomas Eggerman, Austine Moulton	Phillip Snoy	02/23/00	Non-Responsive, DPP	5 USC 552(b)(5)
3144	Document Released in Entirety	7	pgs. 1-7: releasable	Unknown	Unknown	Undated	None	

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3245	Document Released in Entirely	2	pgs. 1-2: releasable	Walt Osborne	Kathryn Zoon	11/23/94	None	
3476	General: CCI: The document contains a chart showing the IND number / sponsor, the product name, indications, status, patients enrolled / treated, adverse events attributed to xenotransport, and comments / review team.	4	pgs. 1-4: releasable with b(4) and b(5) redactions	Unknown	Unknown	Undated	CCI, DPP	5 USC 552(b)(4); 21 CFR 601.51; 21 CFR 20.61, 5 USC 552(b)(5)

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3585	IND G: handwritten notes of telecon between FDA and sponsor re: PERV CCI: PERV testing, sponsors' names, clinical trial	1	pg. 1: b(4) and b(5) throughout entire document	Unknown	Unknown	Undated	CCI, DPP	5 USC 552 (b)(4); 21 CFR 601.51; 21 CFR 20.61; 5 USC 552(b)(5)
3590	Document Released in Entirely	44	pgs. 1-44: releasable	Unknown	Unknown	Undated	None	

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3591	General: Internal Email, re: Review of Sponsor Xenotransplantation Interim Regulatory Authority meeting (closed meeting)  CCI: names of sponsors, PERV testing, cells used; PERT assay	3	pgs. 1-3: b(4) and b(5) throughout entire document	Phillip Noguchi, Army Patterson,	Carolyn Wilson	08/12/98	CCI, DPP	5 USC 552 (b)(4); 21 CFR 601.51; 21 CFR 20.6; 5 USC 552 (b)(5)