

## Safety Review

The side effects of Narrowband UVB are typically rare, mild, and most importantly external. It is safe to use for children, the elderly, and patients who are pregnant, or nursing, and can be used for patients who are HIV+, or who have other conditions such as diabetes.

In contrast, the biologic drugs' safety profile is not as favorable. FDA statistics on adverse events and deaths are shown on charts A & B below. The most common side effects of Narrowband UVB are occasional erythema and dry skin.

**Chart A: Number of Adverse Events** where the Primary Suspect was a Drug

Drug Family	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Grand Total
Oxsoalalen	0	0	1	0	0	0	1	0	1	0	3
Cosentyx	0	0	0	0	0	0	0	0	0	238	238
Protopic	93	48	74	85	49	36	46	74	74	45	624
Elidel	118	67	64	78	349	29	88	18	11	6	828
Raptiva	197	287	183	104	1	1	58	1	0	37	869
Otezla	0	0	0	0	0	0	0	0	213	1662	1,875
Methotrexate	220	295	286	276	262	464	529	466	911	1,622	5,331
Stelara	0	0	0	37	481	1,073	1,237	1,105	1,035	1,523	6,491
Humira	905	1,421	2,632	3,986	4,790	7,472	7,835	7,560	8,457	10,229	55,287
Remicade	3,368	4,080	4,408	4,774	6,302	7,781	9,990	6,390	4,000	4,842	55,935
Enbrel	1,268	2,147	2,562	3,125	3,620	6,700	7,225	10,332	11,169	13,917	62,065
Grand Total	6,169	8,345	10,210	12,465	15,854	23,556	27,009	25,946	25,871	34,121	189,546

\*Although appearing to be the most innocuous of the biologic drugs in the comparison above; Raptiva was removed from the U.S. market on April 8, 2009 due to the risk of PML, a fatal brain infection. Data compiled using MedWatch statistics available at FDA.gov Enbrel is a registered trademark of Amgen, Inc. / Wyeth Pharmaceuticals. Humira is a registered trademark of Abbott Laboratories. Remicade is a registered trademark of Centocor, Inc. Raptiva is a registered trademark of Genentech. Elidel is a registered trademark of Novartis. Protopic is a registered trademark of Astellas Pharma.

**Chart B: Number of Deaths** where the Primary Suspect was a Drug

Drug Family	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Grand Total
Oxsoalalen	0	0	0	0	0	0	0	0	0	0	0
Cosentyx	0	0	0	0	0	0	0	0	0	19	19
Protopic	7	3	8	9	5	6	1	3	4	0	46
Otezla	0	0	0	0	0	0	0	0	1	55	56
Elidel	6	2	9	12	21	5	1	1	0	0	57
Raptiva	36	40	61	35	0	1	79	2	1	57	312
Stelara	0	0	0	2	32	108	96	62	92	106	498
Methotrexate	86	159	89	109	48	179	171	109	152	239	1,341
Remicade	736	778	679	739	675	693	631	368	261	209	5,769
Enbrel	289	366	380	374	429	415	620	1,420	723	772	5,788
Humira	437	487	598	767	899	1,372	1,305	1,079	1,192	1,241	9,377
Grand Total	1,597	1,835	1,824	2,047	2,109	2,779	2,904	3,044	2,426	2,698	23,263