



DCAT Week 2008

Pharma vs The Others: Quality of Scientific Publications

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Thomson Pharmaceutical Services

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Publication Quality



- The state of the industry
- Comparison of Pharma vs non-Pharma sponsored information
- Observations

Scrutiny of the Industry



- Regulatory activity surrounding the use of promotional materials including publications
- Non-disclosure of selected results
- Loss of confidence by public in the pharma industry

WARNING Letters & Untitled Letters



Public Health Service
Food and Drug Administration
Rockville, MD 20857

DEPARTMENT OF HEALTH & HUMAN SERVICES

TRANSMITTED BY FACSIMILE

Cary Raymont
President and Chief Executive Officer
Alcon, Inc.
c/o Alcon Research, Ltd.
6201 South Freeway R7-18
Fort Worth, TX 76134-2099

RE: NDA #21-862
Nevanac™ (nepafenac ophthalmic suspension) 0.1%
MACMIS ID #14150

WARNING LETTER

Dear Mr. Raymont:

The Division of Drug Marketing, Advertising, and Communications (DDMAC), in consultation with the Division of Anti-Infective and Ophthalmology Products, has reviewed a professional sales aid (NPF06500YS) for Nevanac™ (nepafenac ophthalmic suspension) (Nevanac) submitted by Alcon Research, Ltd. on behalf of Alcon, Inc. (Alcon) under cover of Form FDA 2253. This sales aid is false or misleading because it broadens the indication, presents unsubstantiated superiority claims, overstates the efficacy of Nevanac, omits risk information, and presents misleading safety claims, including a dosing claim that is inconsistent with the FDA approved product labeling (PD for Nevanac, Act), 21 U.S.C. §§352(a) & 321(n), and FDA implementing regulations. Cf. 21 C.F.R. §§202.1(e)(5)(iii); (6)(i); (ii) & (vii). These violations are concerning from a public health perspective because they suggest that Nevanac is safer or more effective than has been demonstrated, and they

HUMAN SERVICES

TRANSMITTED BY FACSIMILE

Frank Baldino, Jr., Ph.D.
Chairman and Chief Executive Officer
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355 USA

RE: NDA # 20-717
Provigil® (modafinil) Tablets [C-IV]
MACMIS # 14707

WARNING LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Kurt Orlofski
CEO
Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

RE: ANDA # 88-191
Lindane Shampoo, USP, 1%
MACMIS ID # 15909

WARNING LETTER

Dear Mr. Orlofski:

This letter notifies Morton Grove Pharmaceuticals, Inc. (Morton Grove) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed promotional pieces for Lindane Shampoo, USP, 1% (Lindane Shampoo) issued by Morton Grove and by Alliant Pharmaceuticals, Inc. (Alliant), which until recently marketed Lindane Shampoo on behalf of Morton Grove.¹ These pieces include websites promoting Lindane Shampoo (http://www.alliantpharma.com/alliant_products.html and <http://www.lindane4lice.com>)² and a promotional piece entitled *The Nit Picking News* (LINS 06-602). The websites and newsletter are misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients; include a misleading dosing claim; and overstate the efficacy of Lindane Shampoo. In particular, Lindane Shampoo is plainly labeled as second line treatment, suitable only when other, safer treatments fail or are not tolerated. The materials convey little sense of this limitation and little about the magnitude and nature of the risks associated with the drug. The materials appear to represent an attempt to downplay the significant risks associated with Lindane Shampoo use and encourage wider use, with less care, than is

Are Things Really That Bad?



- Independent assessment of the quality of published literature
- Negative vs positive information

Methodology



- Through the methodologies of the TMMS, we evaluate the quality of included material by:
- Assessing each article, abstract and poster in terms of its scientific content, the appropriateness of the methodology and how well the information has been presented.
- Assigning each study a score (called the Thomson Source Score) ranging from 0% to 100%. 70% or more indicates a well written, thoughtfully designed, scientifically-valid study.

Industry Activity and Quality

*The Organizations that have made the biggest impact in the leading sources of information on medical research
(October–December 2007)*

Sponsor	Number of Sources	Thomson Source Score (%)	Thomson Institutional Recognition Score ²	Ranking During Previous Quarter
Bristol-Myers Squibb	73	77	5621	5
Eli Lilly	72	75	5400	2
Pfizer	67	76	5092	6
GlaxoSmithKline	65	75	4875	4
AstraZeneca	61	75	4575	3
Novartis	57	73	4161	1
Sanofi-Aventis	58	71	4118	7
Novo Nordisk	54	73	3942	10
Merck	44	72	3168	8
National Institutes of Health (US)	47	67	3149	9
Takeda	40	78	3120	11
Wyeth	27	74	1998	NR
Genentech, Inc	27	71	1917	NR
Amylin Pharmaceuticals	21	76	1596	13
Amgen	21	72	1512	NR

Comparison of Strength of Information Pharma vs non-pharma 4Q07

Sponsor	Number of Articles	Mean Source Score
Pharma	896	75
non-Pharma	410	72

P=0.0004

Comparison of Strength of Information Pharma vs non-pharma All of 2007

Sponsor	Number of Articles	Mean Source Score
Pharma	2550	75
non-Pharma	1014	71

P < 0.0001

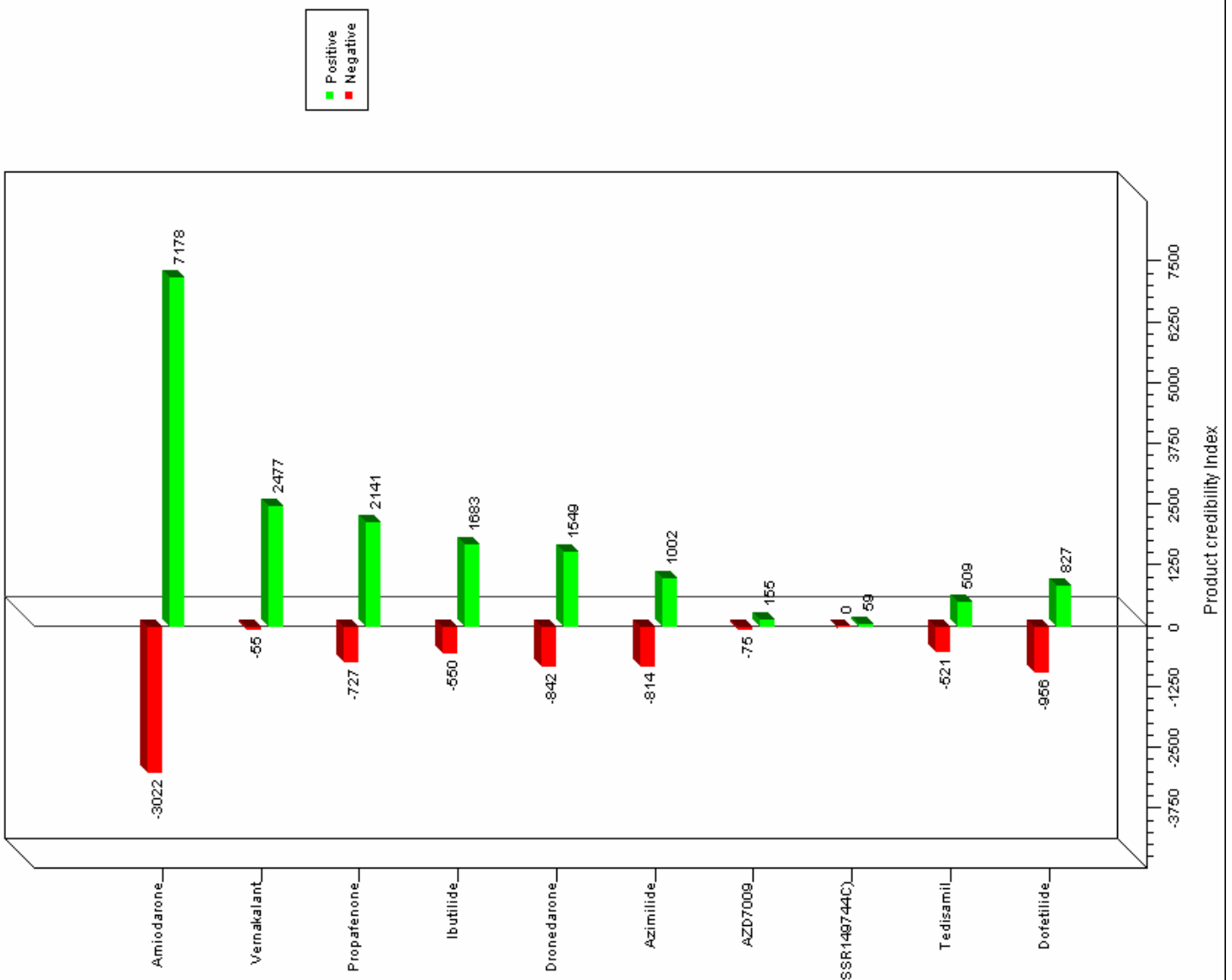
Year-On-Year Comparison

Sponsor	2006 Mean Source Score	2007 Mean Source Score
Pharma	78	75
non-Pharma	57	72

Negative vs Positive Information

- Perception that only positive information is discussed about therapies
- Pharma-sponsored negative information is readily available

1.6 Product Credibility Index



Azimilide (P&G Pharmaceuticals)(2004-Present)

	No of Messages	%
Positive	6	35%
Neutral	6	35%
Negative	5	30%

Observations

- Published scientific information is generally of high quality
- Pharmaceutical companies sponsor well written, thoughtful sources of information
- Mean Source Score analysis suggests small but consistent differences in favor of pharma-sponsored information.
- Industry-Sponsored information can be well-balanced