

To: FDADockets@OHRM-MAIL@FDAOC  
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Certify: N  
Subject: FDA and Off Label use  
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Attached: None

The recent decision in WLF v Friedman (WLF PRESS RELEASE ATTACHED) does not go far enough to remove serious, unnecessary and now silly barriers to commercial free speech. Indeed the Court's order needs to be expanded to permit more information for consumers and professionals alike..

That decision orders FDA to permit companies to distribute medical textbook materials as well as articles from peer reviewed journals about "off -label" or unapproved uses of drugs to physicians (so called learned intermediaries). It also loosens FDA control over manufacturer-sponsor Continuing Medical Education at which off-label uses are discussed.

I advocate the expansion of the order to allow free distribution of all materials about a drug by the manufacturer under a fair balance rule is based upon facts that any court may take judicial notice, THE EVOLUTION OR REVOLUTION IN INFORMATION EXCHANGE in the electronic era. As one friend at our local bellco said to me yesterday "You Ain't Seen Nothing Yet, Here Let Me Show You."

It is time for the Gatekeepers (Kafka's old enemy of intellectual freedom) of the world to recognize that "censorship" has become impossible, is impossible. The remedy for potential and real misunderstanding or misinformation caused by both commercial information, academic information and even lay press is educational responsibility placed in the hands of the private sector with some guidance from a global regulatory authority which requires "fair balance."

This solution not only targets misinformation by the commercial sector but places "RESPONSIBILITY" for fair balance commentary on the literature out there on library shelves and both of wood and virtual reality.

Mired in this case is a lack of recognition and real understanding by the FDA, its lawyers and regulators that the dynamics of the opening of the Internet to the private sector a few years ago, which they too recognize has changed the world, and with it gives us the opportunity to bring creative solutions to and old problem. That problem is both the problem of "false and misleading advertising and labeling" by the commercial sector and misinformation in the clearly unregulatable "press (books, articles, broadcasts) not under the control of manufacturers of drug products. Indeed the former may be more misleading than the latter.

What has changed dramatically since this litigation began four years or more ago, and is changing this minute is the speed and volume of information present at our finger tips or soon our voice commands (for those like me that type poorly). We have the "wire" provided by the internet and the software that allows us to create the Word Wide Web and the volumes of information poured onto the net by the millions of new subscribers added monthly.

The Order and decision of the District Court in WLF v. Friedman does not

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take these facts, properly judicially noticed, into account. Nor does FDA properly identify the problem it is addressing in a real world context. Hence the solution it advocates faces no reality.

Strangely and with an eerie feeling that someone(s) is looking over our shoulders, is the fact that the only people that address the problem and provide the ground work for a solution lived ten score and one year ago when the Constitution was written and ratified. They are the authors and framers of the First Amendment the Constitution. (In my opinion Dr. Franklin and Mr. Jefferson, both had the view of this electronic future in their minds when they advocated our free speech rights. Indeed Dr. Franklin was probably "shocked into it.")

Let's look at the facts.

Access to information in the Virtual Library of "Alexandria" began in the late sixties early seventies. NASA developed a program called Recon to manage text information. Lockheed owned the software and worked with text abstract publishers and thus Dialog was created.

Jerry Rubin then created Lexis and eight years later West created West-Law. Obviously we as barristers are well aware of the potency of these private line database services no accessible over the Internet.

But that was just the beginning.

The Distric Court's decision takes a broad view of the capacity of Physicians (learned intermediaries) and and narrow view of consumers' capabilities to do research on the "on-line" services as well as free data available over the Internet and the WEB. For example one may search the National Library of Medicine database, Embase (Reed Elsvir), Nexis, Martindale, Stedman's, The Physicians Desk Reference (PDR), FDA's own Internet site, Healthfinder.org (HHS), and a myriad of other health sites for information about both approved and unapproved uses of drugs. Indeed "we" medical webmasters now have over 100 participants in a medical webmaster discussion group which link to or provide information to anyone that turns on Netscape or Internet Explorer. Our members cover every area of medicine and pharmacology on a GLOBAL BASIS.

These websites offer , text, graphics and voice messages, and even courses.

With all respect to FDA policy makers, they are either not users of the information, or they are so consumed with their tasks that they are like a Giant Ostrich with its head in the sand.

To think that we can prevent doctors, health practitioners and consumers (many of whom know more than doctors) from getting information about off-label use is a fantasy.

I am told that one third of the questions addressed to reference librarians is about health. A recent NY Times article said 2/3rds of Internet queries were about health.

In the earlier days of the web I had visitors to my Internet site on FDA regulation send me e-mail querying me about sources of information on rare diseases, cancer therapies etc. I just pointed them to the other health sites (and there were then few) and "trained" them on how to find the information on the WEB with the indexing services, themselves.

Indeed we all hear stories today about consumers who are ill with rare

diseases, serious diseases such as breast cancer, heart disease, chronic fatigue syndrome who often know more than physicians about the disease and methods of treatment by searching the Internet. It is the consumer who has generated the demand and interest in Chinese Medicine, alternative medicine, herbs and dietary supplements. Even Dr. Art Eulien now admits that he was wrong about dietary supplements (consumers knew). Information (quality and poor quality) is available on all these products today on the new Library at Alexandria -- THE WORLD WIDE WEB.

While our founding fathers (except, perhaps Jefferson and Franklin) never perceived of the changes in technology that would transpire in two centuries (unless they had a time machine) they provided us with the First Amendment both for political and commercial free speech.

In view of the law and cases on the law, as so adequately cited and set for by Judge Lamberth in his decision, we must conclude that reality of facts (some not before the Judge) forces and ineluctable conclusion that the order is too narrow.

We do not need and it is useless to impose a learned intermediary solution, between manufacturers, physicians and consumers to solve the problem of false or misleading information.. It accomplishes NOTHING but filling the CFR with more trash.

So what is the real problem and what is the solution?

Dean Robert Childress taught us at NYU Law school in our Remedies course that a decision and order must narrowly meet all objectives for solving a problem within tenants of public policy. Thus we don't stop a speeder by shooting him. Certainly that is over-kill.

So what is the real problem? The real problem is all the information out the cyberspace and paper libraries that is accessible to anyone. This stream of literature whether disseminated by manufacturers or citizens may be false or misleading.

The remedy is simple and fits within the context of the Prescription Drug Amendments of 1962, Senators Kennedy & Hatch. Permit manufacturers to add information about off label use and other information about their product in the Physician Label and the long awaited Patient Label in the context of the fair balance requirement. And on the Internet let them elaborate as they wish within the same context of Fair Balance.

What better authors and editors of information about prescription and nonprescription drugs than the drug companies whose researchers know their product and the disease, symptoms or end points.

FDA wake up (and FTC please listen). Deal with reality and withdraw the June 1998 rulemaking which seeks to impair and impose even more restrictions on off-label information. Repropose a regulation that provides a solution within Constitutional constraints and good public policy.

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consulted with FDA on their Website and they are a customer of a database product. He has consulted with the FTC on FDA regulation of health claims and OTC drugs.