

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF NEW YORK

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: Index No. 766,000/2007  
IN RE: NEW YORK RENU WITH MOISTURELOC :  
PRODUCT LIABILITY LITIGATION :  
: :  
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THIS DOCUMENT APPLIES TO ALL CASES  
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IN THE UNITED STATES DISTRICT COURT FOR  
THE DISTRICT OF SOUTH CAROLINA  
CHARLESTON DIVISION

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: MDL No.: 1785  
IN RE: BAUSCH & LOMB CONTACT LENS :  
SOLUTION PRODUCT LIABILITY LITIGATION : C/A No. 2:06-MN-77777-DCN  
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THIS DOCUMENT APPLIES TO ALL CASES  
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**MEMORANDUM OPINION AND ORDER ON REDACTION OF ZIP CODES  
IN ADVERSE EVENT REPORTS**

**DANIEL J. CAPRA, SPECIAL MASTER:**

In this litigation, Defendant Bausch & Lomb is providing Plaintiffs with copies of adverse event reports, asserting failure of the medical devices at issue in this litigation. These adverse event reports were voluntarily submitted to Defendant by users and providers. *See Adcox v. Medtronic, Inc.*, 131 F.Supp.2d 1070 (E.D. Ark. 1999) (discussing voluntarily submitted adverse event reports). The adverse event reports contain information identifying the provider and the user. Defendant has redacted this identifying information, with the exception of the State in which an identified person resides. The parties dispute whether Defendant is required to redact Zip Code information.

Defendant argues that redaction of Zip Codes in the adverse event reports is required by 21 C.F.R. § 20.63(f), which provides as follows:

(f) The names and any information that would identify the voluntary reporter or any other

person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

The parties and the Special Master have searched for case law covering this subject, and no case has been found that considers whether disclosure of Zip Code information is barred by § 20.63(f).

Plaintiffs argue that disclosure of Zip Codes will be helpful to them in determining whether there are “clusters” of injuries in any particular locality, and that concerns about disclosure are unwarranted because Zip Code information cannot be used to identify a specific individual. Defendant argues that at least in areas where there are few users and providers, disclosure of a Zip Code may be tantamount to disclosure of identity.

The arguments are overbroad on both sides. If the justification for disclosure is that plaintiffs are looking for clusters, it would not seem necessary to disclose the Zip Codes for *all* the adverse event reports, but only for those in which a large number of reports come from the same Zip Code. Even then, Zip Codes are not allocated in a way that would give much probative information about a cluster. Zip Codes are not uniform geographically; clusters may cross state lines or Zip Code lines, and so forth.

On the other hand, Defendant’s justification for redacting Zip Code information is overbroad, because there are likely to be some Zip Codes (such as that of an office in New York City) in which the number of users and providers is so great that there will be no way that the Zip Code information can be used to track down an individual. Yet the fact remains that there will be some Zip Codes (such as that of a small town with its own Zip Code) in which disclosure of Zip Code information might be tantamount to disclosure of only one or a few individuals.

The question, then, is whether it is worth the effort to proceed Zip Code by Zip Code. On Defendant’s argument, that would mean redacting those Zip Codes in which there are only a small number of individuals — whatever number that may be. On Plaintiffs’ argument, that would mean disclosing Zip Codes when there are enough reporting individuals to form a cluster — whatever number that may be. To state these options is to refute them. The costs of such an indeterminate winnowing process outweighs the benefits. So the proper result is to order disclosure either of all Zip Code information or none of it.

I conclude that no Zip Code information should be disclosed. The importance of protecting the privacy interests of voluntary reporters justifies a broad reading of 21 C.F.R. § 20.63(f). The regulation specifically states: “Information that would identify the voluntary reporter or persons

identified in the report includes, *but is not limited to*, the name, *address*, institution, or any other information that would lead to the identities of the reporter or persons identified in a report.” (Emphases added). The list is only illustrative and I conclude that this is a direction to the disclosing party to go further and redact other information that is similar to the specific types of information listed. Certainly a Zip Code is at the very least similar to an address. Indeed most people would think that a Zip Code is now an inherent part of an address. So a fair reading of the regulation leads me to conclude that redaction of Zip Code information is mandated; and even if not mandated, redaction of Zip Code information is preferable to disclosure of all Zip Code information; redaction is also preferable to an indeterminate case-by-case winnowing process.

I therefore conclude that Defendant is entitled to redact all Zip Code information from the adverse event reports.

### **Order**

Plaintiffs are not entitled to disclosure of any Zip Code information included in the adverse event reports produced by Defendant in this matter. Plaintiff’s request to order Defendant to provide such Zip Code information is denied.

SO ORDERED:

A handwritten signature in black ink, appearing to read 'Daniel J. Capra', written over a horizontal line.

Daniel J. Capra  
Special Master

Dated: New York, New York  
March 3, 2008