



1           2.       Assuming *arguendo* that a distributor has an independent duty to warn in a strict products  
2 liability case (where the underlying theory is a failure to warn), *cf. Persons v. Salomon N. Am.*, 217 Cal.  
3 App. 3d 168, 178 (1990) (noting that company, which “was in the business of renting skis and  
4 bindings,” “had an independent duty to exercise reasonable care in supplying this equipment and was  
5 itself subject to strict liability for failure to warn its customers of the dangerous propensities of articles  
6 it rented”), (a) what should McKesson have done in the instant cases to satisfy that duty and (b) how  
7 are those actions not inconsistent with or prohibited by federal law, including but not limited to 21  
8 U.S.C. § 355 and 21 C.F.R. § 314.70(a)? *Compare Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011)  
9 (deferring to the FDA’s position that a Dear Doctor letter qualifies as labeling; stating that “[a] Dear  
10 Doctor letter [from a generic manufacturer] that contained substantial new warning information would  
11 not be consistent with the drug’s approved labeling”).

12           3.       What weight should the Court give the FDA’s comments, in conjunction with its  
13 promulgation of certain labeling and advertising regulations in 1979, *see* 44 Fed. Reg. 37434, 37447  
14 (June 26, 1979) (stating that “[t]he addition to labeling and advertising of additional warnings, as well  
15 as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters to  
16 health care professionals (e.g., ‘Dear Doctor’ letters containing such information) is not prohibited by  
17 these regulations”), particularly in light of the Supreme Court’s decision in *Mensing*?

18           **By July 10, 2012**, Bristol-Myers shall file in the eight related cases an omnibus supplemental  
19 brief on the following issues:

20           1.       For those actions Plaintiffs claim McKesson could have taken to satisfy its duty to warn,  
21 what *specific* federal statutes or regulations barred or made it impossible for McKesson from taking  
22 those actions? The Court seeks more than a general reference to the FDCA’s labeling laws.

23           2.       What weight should the Court give the FDA’s comments, in conjunction with its  
24 promulgation of certain labeling and advertising regulations in 1979, *see* 44 Fed. Reg. 37434, 37447  
25 (June 26, 1979) (stating that “[t]he addition to labeling and advertising of additional warnings, as well  
26 as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters to  
27 health care professionals (e.g., ‘Dear Doctor’ letters containing such information) is not prohibited by  
28 these regulations”), particularly in light of the Supreme Court’s decision in *Mensing*?

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Plaintiffs' brief shall be no longer than twelve (12) pages; Bristol-Myers's brief shall be no longer than eight (8) pages.

IT IS SO ORDERED.

Dated: June 26, 2012



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EDWARD M. CHEN  
United States District Judge