

Side Effects Include Fines

By Reg P. Wydeven
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In the summer of 1991, I had just graduated from high school. That summer marked the release of the classic film ‘Boyz ‘n the Hood.’ The John Singleton movie focused on three young African-American men growing up in inner city Los Angeles. In addition to every day struggles of parents and school, Ricky, Dough Boy and Tre are also faced with drugs and drug violence.

Singleton was nominated for two Oscars for writing and directing the movie. The film was both a critical and box office success. It really resonated with me, for I saw guys my same age on the big screen, yet their world couldn’t have been more different than mine.

The movie exposed the country to the reality of south central L.A. It also introduced us to the prototypical gang member: it seemed everyone wore a baseball hat, carried a gun and wore a pager. A pager was critical to a gang member, especially a drug dealer. It alerted him to shipments coming in, customers wanting to buy or raids by the police. This telecommunications device was critical for pushing drugs.

It’s been more than 20 years since ‘Boyz ‘n the Hood’ came out, but some things never change.

Last month the U.S. Food and Drug Administration released proposed guidelines regulating tweets by companies that manufacture drugs or medical devices. In addition to touting the benefits of their wares, drug companies would be required under the new rules to also tweet about the risks of their products.

At a minimum, pharmaceutical companies would have to disclose the most serious risks associated with their drugs, including those known to be fatal or life-threatening. In addition, companies would have to tweet about their drugs’ side effects and the warnings printed on the drug’s label that have been approved by the FDA. Finally, a link to a website elaborating on the risks and benefits of the drug would have to be included in the tweet.

The FDA explained that tweets about drugs or medical devices must “present both benefit and risk information.” The tweets must be truthful, non-misleading and ensure that the “indicated use of the product and the risks associated with use of the product” be included.

Drug companies are obviously concerned, as tweets are limited to 140 characters. Trying to squeeze all the advantages and disadvantages of a drug into a sentence or two would be a daunting, if not impossible task. The FDA rules would also not permit a company to simply include a link to a website advising of the risks – that must be listed in the tweet. The FDA did not indicate whether common twitter abbreviations are permitted, which meant no drug companies were lol.

Companies are allowed, however, to submit their tweets to the FDA for approval before posting. If the new guidelines are approved, they will go into effect in 90 days.

Drug companies vehemently oppose the new rules. Representatives for Viagra purportedly indicated that the guidelines were even too stiff for them.

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