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LETTERS

FDA LETTERS AND SPONSOR ANNOUNCEMENTS

From the FDA, we still hear mostly thunderous silence

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Lurie and colleagues' comparison of FDA letters not approving applications for new drugs and associated public announcements from sponsors provides a valuable but rare peek behind the Food and Drug Administration's "iron curtain." The discussion section begins, "our analysis found that the FDA's reasons for not approving marketing applications for new molecular entities are not being fully conveyed to the public."[1] On the basis of the striking results, this seems an understatement. Consistent with research using other FDA document types,[2-6] much of the information to which clinicians have access comes to us (or doesn't) only after it's been filtered by vested interests.

Thanks to this excellent paper, we now know that seven drugs had worrying mortality rates. But because this and other results were reported in aggregate and were de-identified, clinician-readers are left in the dark about information that could be crucial to safe prescribing. We can only hope that the FDA exercised due diligence and ensured that any drug related safety signals were prominently disclosed in the product labelling.

Why does the FDA remain silent on such important matters? A key reason is how it has interpreted and implemented exemption 4 of the Freedom of Information Act (see section on policy considerations). In a 2006 article, the lead author of the current paper referred to "the imposing edifice of the confidential commercial information exemption" in an article entitled "Sometimes the Silence is Like Thunder."[7]

The current paper provides a welcome respite from the usual thunderous silence. The referenced Transparency Task Force made several recommendations consistent with a re-interpretation of exemption 4, giving greater consideration to public health relative to drug company interests. But since a 2010 report on public disclosure,[8] there has been little apparent follow-up, raising concerns that the agency is failing to escape its tradition of translucency.

Competing interests: I was employed at the Food and Drug Administration as a medical officer from 1998 to 2001.

Full response at: www.bmj.com/content/350/bmj.h2758/rr.

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