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Regulating nanomedicine

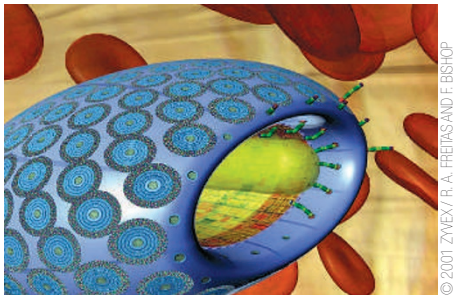
Given that stringent safety checks already exist for new medicines, does the FDA really need a nanotech task force?

Take two of the most controversial (but largely unrelated) issues grabbing recent headlines: safety issues surrounding the use of nanotechnology, and the recall of drugs with unforeseen side effects by the US Food and Drug Administration (FDA). Put these two together with nanomedicines lined up to get through FDA regulatory approval and you get the potential for a double knee-jerk reaction from the public.

In such an atmosphere of paranoia where pre-emptive measures are the norm, the FDA responded to the potential safety risk by setting up a Nanotechnology Task Force last August. This decision may come as a bit of a surprise to some. Why does the FDA need to set up such a task force now? Does the agency not already have a system in place to ensure that any of the drugs or cosmetics getting through its offices are indeed safe and effective? Or is it Andrew von Eschenbach's prerogative, as new FDA commissioner, to leave his mark on the agency by picking on an area that's guaranteed to touch people's imagination?

Far from being a public-relations stunt, this decision seems to reflect a return to normality at the agency, which has recently been plagued by a lack of leadership. Currently, the FDA does not have specific guidelines in place to regulate nanomedicines (drugs more complex than traditional ones); they are subject to the same stringent rules as any other new drug. But existing regulations may not be enough. A few months away from giving its conclusions, the task force is mandated to bring recommendations on updating guidelines for nanomedicines, should it identify specific needs for doing so.

Key areas of interest for the task force are nanoparticle characterization, detection, and their fate in the human body from both administration in patients and from the environment. Yet, reliable methods of assessing toxicity and environmental exposure to nanomaterials such as self-assembled complexes, dendrimers or inorganic nanotubes have yet to be developed. In a recent commentary[1], Andrew Maynard urges for such research to be carried out, as the potential for nanohazards have already been identified[2].



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Is the Nanotechnology Task Force doing enough to convince the public that nanomedicine is safe?

The FDA has good reasons to prepare for the next generation of nanomedicines. Three quarters of research studies, and 59% of patents in the field of nanomedicine are in drug-delivery systems; other applications include nanoscale therapies, *in vivo* imaging agents, *in vitro* diagnostics sensors, biomaterials and active implants. Knowing that about half of the patent filing is made in the United States, the FDA would be sensible to anticipate the demand. What's more, with at least 207 companies pursuing nanomedicine projects and 38 nanotechnology-enabled products currently on the market bringing in $6.8 billion in sales in 2004, the sector is deemed to grow to $12 billion by 2012.

In Europe, the future development of nanomedicines would benefit from further collaboration between academia and industry[3,4]; the European Medicines Agency (EMEA) has already installed its own Innovation Task Force in 2005 to anticipate the regulatory needs of emerging therapies. But, so far, the absence of sufficient data has prevented the group from suggesting any changes to existing regulations. Clearly, insufficient knowledge about such products is problematic for the FDA too.

Independently of the outcome of the FDA task force recommendations, there is very little hope that public fears could be alleviated until enough data on this emerging class of products have been gathered and after these products have been through approval. Even then, as only a few products are likely to go through every year, reaching a consensus will prove elusive. This chicken and egg situation, albeit typical of emerging technologies, has forced the FDA to adopt a high-profile precautionary approach in the hope of countering the risk that negative public opinion could slow down the approval process or lead to rejection of novel nanomedicines altogether.

Ironically, it could have exactly the opposite effect. If the next generation of products has to undergo stricter testing than already approved nanomedicines, the process could prove even more lengthy and costly than at present.

References

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