# Patient expresses concern about lack of data on biological drugs

April 18 2013

Image courtesy of Blausen Medical

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(HealthDay)—A patient with Crohn's disease is concerned about the attempt by the makers of adalimumab to prevent disclosure of trial data submitted during the drug's approval process, according to a personal view piece published online April 16 in *BMJ*.

Alex Lomas, a patient with Crohn's disease from London who has been taking adalimumab for three years with beneficial results discusses the lack of trial data available on biologicals.

Noting that part of the National Institute for Health and Care Excellence's approval for use of adalimumab for Crohn's disease was the recommendation to set up a registry to track long-term outcomes and

relapse rates after treatment withdrawal, Lomas reports that registries are fragmented or are still at pilot stage. He adds that the attempt by AbbVie, the maker of adalimumab, to prevent the European Medicines Agency from disclosing recent trial data submitted during the drug's approval process is cause for concern and is preventing patients and health care providers from making informed decisions about the use of this treatment.

"As the drug industry and medical profession as a whole move towards the registration of all trials, and the publication of all trial data—in no small way thanks to the All Trials initiative (www.alltrials.net)—this decision by AbbVie is a backwards step and is offensive to trial participants, patients, and the wider public who ultimately pick up the tab," Lomas writes.

**More information:** Full Text