Politics and the FDA

By David Shlaes — August 24, 2020

If you're someone who believes that the Food and Drug Administration is purely guided by science and that politics has never influenced its decisions, we likely live on different planets. As for some background, here's some recommended reading to go with our overall perspective on this issue.
If you are one of those who believe that the FDA is purely guided by science and that politics
never has influenced its decisions or its very structure, you and I live on different planets. By way
of background, I recommend some reading. First, there is a definitive history [1] of the FDA written
by Phil Hilts on the occasion of the FDA’s 100th anniversary in 2003. He notes that the very early
beginnings [2] of what was to become the FDA goes back to Charles M. Wetherill – a chemist in the
Department of Agriculture in 1862 who began to analyze substances in foods for toxins. Then
came [3] Harvey Wiley who started to try and convince lawmakers to act against the quack
remedies harmful nutritional ingredients that had proliferated during the 19th century. Wiley finally
was appointed chief chemist in the Department of Agriculture around 1880. At the turn of the
century, he established the poison squad – a group of young volunteers who tested foods and
food additives on themselves (!). Wiley wrote much of the Food and Drugs Act of 1906 that was
signed into law by Teddy Roosevelt. Looking back on all this early history, the laws passed after
the civil war were often the result of political pressure from the obvious adverse effects of the
various snake oils and remedies being promulgated at the time and that had resulted in sickness
and death of US soldiers during and after the war.

Back then, the early FDA could not actually pursue manufacturers or products until they had
shown that a problem actually existed either via showing clinical harm or by demonstrating the
presence of known dangerous substances. This is similar, by the way (and to the horror of many of
us) to the way “nutritional supplements” are regulated (not) today largely thanks to Orin Hatch.

This early approach changed dramatically in 1962 with the passage of the Kefhauver-Harris
amendment to the Food and Drugs Act. The impetus for this change was the devastation of birth
deformities as the result of the use of thalidomide to control the nausea of pregnancy and the
resulting political pressure for change. This amendment required manufacturers to demonstrate
not just safety but also the efficacy of any proposed therapeutic.

Fast-forward to the early 2000s and clinical trials to prove the safety and
efficacy of new antibiotics. For years, the Infectious Diseases Society of America and the FDA
collaborated in the promulgation of guidelines setting out the requirements for the design of these
studies. Starting around 2000, the statisticians at FDA began to balk at the fundamental statistical
foundation for the approach that had been used since the days of penicillin. That approach called
for studies comparing a new antibiotic to an old, approved, and standard of care antibiotic where
the new drug had to be shown to be not inferior to the standard treatment. This is quite different than other clinical domains where new therapies are shown to be superior to placebo. As we all know, it is generally not acceptable to treat patients with a life-threatening disease (many if not most bacterial infections) with a placebo when we know that a safe and effective therapy already exists. Hence the so-called non-inferiority approach. The FDA then gradually tightened the statistical margins required resulting in increased costs of trials, lengthened time to market and decreased profits for new antibiotics. Then came the Ketek scandal of 2006 and the major involvement of politics in FDA “business.” Ketek (telithromycin) is an antibiotic developed by Sanofi for the treatment of pneumonia, sinusitis and bronchitis. It was approved in the US in a twisted set of data evaluations by the agency where, virtually uniquely, post-market safety data from Europe where the drug had already been on the market for a period of time was used to help justify the approval. After a year or two on the US market, several cases of severe liver injury were linked to Ketek and the scandal was born. Public Citizen cried foul relying on FDA insiders who objected to the way Ketek was approved to begin with. Public Citizen in turn pressured Congress, especially Reps. Markey and Grassley, to investigate the FDA. Markey and Grassley threatened the FDA with an investigation. This resulted in FDA panic mode as they feverishly began to assemble all the documents and materials that such an investigation would require. Rather than face the congressional investigations threatened by Markey and Grassley, FDA reacted by essentially carrying out their own investigation in public. There they crucified not only their own officials who led the approval of the drug, but also the clinical trial requirements for antibiotics. The latter response led to a point where it was no longer possible to carry out new antibiotic development and therefore where new antibiotics no longer had a clear path to approval. And all this was clearly based more on politics than the cold hard facts of the science. The FDA lost many dedicated and experienced antibiotic experts as a result of the Ketek scandal. This is all detailed in my book [4] (you can just download the chapter on FDA if you want). As we all know, all’s well that ends well – but that was after at least six years of antibiotic development drought and the loss of hundreds of antibiotic researchers.

Fast forward to COVID. OK. Political influence might be erring on the side of less scientific stringency as opposed to more stringency – but there is no doubt that the FDA, as much as they claim to be science-based, is susceptible to political pressure. And this is nothing new . . .

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