Bioethical accreditation or rating needed to restore trust in pharma

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After years of decline in the public eye, drug companies should implment a bioethics accreditation or rating program to help appropriately restore the industry's good name and improve its effectiveness in advancing global health and new treatments.

The pharmaceutical industry was once among the most admired industries on the planet. Today, it is heavily criticized and distrusted, with only 12% of people in the US believing that drug companies are generally honest and ethical, according to a Harris poll published late last year. Countless experts have raised this problem before, and drug companies have attempted numerous remedial strategies to address bioethical concerns and repair trust deficits. Nonetheless, the mistrust persists, arguably weakening the effectiveness of these important institutions. Is there something new that companies can do to demonstrate the quality of their processes and genuinely earn back our trust? I believe there is.

The drug industry should voluntarily implement a bioethics accreditation, certification or rating system to help companies assess and improve the quality of their services and organizational processes. Such a system would also increase transparency, accountability and awareness of best practices, as well as appropriately improve public confidence where merited.

Accreditation systems originated close to 100 years ago to aid surgeons in maintaining safe working conditions in hospitals. Today, these and other rating systems often improve and help to demonstrate the quality of schools, foods, toothpastes and home goods (think Good Housekeeping Seal) and can serve as indicators of a product's general environmental impact. In a similar vein, through the nonprofit Bioethics International and in tandem with the Edmond J. Safra Center for Ethics at Harvard University (with funding from the Susan G. Komen Foundation and the Raskob Foundation), I am working to pilot such a system for the pharmaceutical industry to address prominent bioethical concerns.

To take the complex ethical process of drug discovery, development, marketing and delivery and translate these things into to a pass-fail or gold-star rating system, one can follow a common process for creating such evaluation programs. This involves cataloging stakeholders' main bioethical concerns about companies, compiling standards that can address those primary concerns and developing methodologies to evaluate how a company aligns its practices with those standards.

The bioethical concerns drug companies need to tackle to receive high regard in today's marketplace fall within four categories: the design and management of clinical trials, the fate of trial results upon study completion, corporate marketing strategies and the accessibility of medicines. Accreditation and rating standards that addresses these four categories of concern can evaluate each company's processes and outcomes either according to what is already expected of it or according to higher expectations that the industry and rating agency sets internally. For example, to address concerns that companies suppress and manipulate unfavorable trial results or publish them in a misleading fashion, baseline standards would ask that companies follow Benjamin Franklin's maxim, "to study, to finish [and] to publish." In other words, companies should, at the very least, register trials and disclose trial results in a timely fashion, as required by federal regulations in the US. Standards can also be culled from the codes of conduct of the industry's own trade association, the Pharmaceutical Research and Manufacturers of America, from other prominent guidelines and from corporate best practices. GlaxoSmithKline, for example, committed last month to the higher standard of publishing all clinical study reports for approved or discontinued drug candidates.

Herein lays a great impasse between critics and the industry. On the one hand, many companies report that they are consistently meeting or exceeding current standards and that violations are outliers or issues of the past. On the other, critics follow the contradictory evidence, such as a 2009 study[1] showing that less than half of surveyed trials were adequately registered and a 2012 study[2] showing that only one in five trials subject to mandatory reporting had met the obligations to post results on sites such as ClinicalTrials.gov. Accreditations, certifications and rating systems can go a long way in addressing this impasse by discouraging deficiencies and recognizing genuine quality processes and performance.

A suitable program for the pharmaceutical industry, described in broad strokes, would probably involve two steps. First, drug companies would complete self-assessment applications rating how they perceive themselves to be meeting standards and providing evidence of implementation. This includes listing all employees responsible for implementing each standard, from the supervisory and board levels through the operational and execution levels. Second, companies would undergo on-site and internal reviews in which employees and possibly external third parties are interviewed and surveyed to ascertain whether the companies are indeed doing what they say they are doing in the self-assessment applications. If the companies satisfactorily pass both evaluations, they are then awarded an accreditation and the use of a 'seal' for a period of time, renewable upon review every three years.

The seal may signal to stakeholders that a drug company has reasonably and transparently addressed prominent bioethical concerns and met certain quality standards. This 'proof point' can be a powerful communication tool for companies as well as a powerful choice or information tool for stakeholders. At a time when the industry is facing increased risks of regulation and sanctions along with a steady decline in public trust, the need for such a reliable metric has never been higher.

I am now actively seeking (and in dialogue with) industry members interested in joining efforts to refine, promote and pilot this innovative program. For the good of the industry and the good of public health, I hope pharma executives will see the benefit of actively implementing a robust bioethics rating system.

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