SMARTER STATE CASE STUDIES

HEALTH AND HUMAN SERVICES: HHS PROFILES

Using Expert Networking to Improve Safety and Efficiency of Medical Device Review

TALENT BANK

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SMART CITIZENS SMARTER STATE

BASIC INFORMATION

Owner

Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services

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Project Summary

An expert network for the regulatory review of medical devices

Sector

Health

Audience

Employees of the Department of Health and Human Services

Problem that it is trying to solve

It is difficult to quickly convene a qualified group of reviewers for the diversity of new medical devices coming to market.

Platform

Customized version of Harvard Catalyst Profiles

Design basics

Employees create profiles drawing from a number of data sources describing their skills and experiences. Representatives of the Office for Device Evaluation (ODE) use those expertise profiles to identify the most qualified individuals to participate in the regulatory review of a given medical device.

KEY TAKEAWAYS

What's new?

Previously there was no rapid, systematic way for the ODE to identify capable reviewers within HHS – resulting on a reliance on the "rolodex" approach involving the usual suspects.

Incentives for participation

The incentives for an individual to participate in HHS Profiles are threefold: 1) recognition of high-level departmental buy-in and interest in the tool; 2) the opportunity to play a meaningful part in improving public health; and 3) leveraging an outlet for articulating and sharing professional expertise.

Challenges

The central challenge for the initial HHS Profiles pilot involves the translation of a given medical device to be reviewed into a collection of relevant skills or knowledge areas which can be used as search parameters on the platform.

Anticipated impact/Metrics

HHS Profiles will seek to increase the speed and effectiveness of the regulatory review of medical devices. Metrics of success will range from the diversity of disciplinary backgrounds represented in reviews to the average time required for the entire review process.

Why is this project interesting?

HHS Profiles is a clear example of the potential impacts on public life of better matching the supply of expertise within government (i.e., medical experts within HHS) to the demand for expertise in government (i.e., the need for qualified regulatory reviewers of an innovative new medical device).and searching for expertise, that can originate a wide variety of use cases.

It is capturing expertise from institutional data such as human resources data on previous projects and positions.

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THE CONTEXT

The FDA's Center for Devices and Radiological Health (CDRH) manages the process of pre-market approval and post-market review of all medical devices. CDRH ensures that "patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products," and facilitates "medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and ensuring consumer confidence in devices marketed in the U.S." [1]

Every year, the CDRH evaluates thousands of devices of varying degrees of patient risk and complexity – many of which employ novel technology. To ensure the safety and efficacy of these products, the FDA is faced with the challenge of finding the right expertise to help it quickly and effectively assess new products. The pathway to regulatory review and compliance for low-risk items like tongue depressors is straightforward. But life-sustaining or high-risk devices such as pacemakers and breast implants require judicious and timely Premarket Approval (PMA) by those with the right know-how. If these medical devices reach patients prior to being properly tested, there may well be very real human costs.[2]

Unlike post-market reviews, the PMA process is undertaken exclusively by internal staff. Previously, the FDA had wrestled with the idea of allowing those outside the agency more broadly to review medical devices, but this foundered out of a fear of conflict of interest and undue influence. Hence the agency has to rely upon its own internal staff augmented by some outside experts, who are hired as temporary employees to man these review panels. As is common in many governmental practices, such as patent examination or regulatory drafting, the FDA is faced with the task of evaluating large quantities of complex information with resort only to a too-small pool of people lacking the requisite diversity and laboring under the strain of too much work.[3]

Traditionally, reviews are undertaken by a set of "usual suspects" identified by staff from the FDA Office of Device Evaluation (ODE).

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1   http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/

2   Beth Simone Noveck, "Bridging the Knowledge Gap: In Search of Expertise," *Democracy* 34, Fall 2014, http://www.democracyjournal.org/34/bridging-the-knowledge-gap-in-search-of-expertise.php?page=all.

3   Beth Simone Noveck, *Smart Citizens: Smarter State: The Technologies of Expertise and the Future of Governing*. Cambrigdge: Harvard University Press, 2015.

THE CHALLENGE

In its regulatory review efforts, the FDA confronts several challenges related to[4]:

✔ **Agility** – Finding and convening a qualified regulatory review panel can take as long as nine months. The FDA has also seen a rapid increase in new medical devices being developed and submitted for review: In 2010 and 2011, an average of 49.5 high-risk medical device recalls were initiated, compared to an average of 24 over the three preceding years;

✔ **Expertise** – The current pool from which experts are identified is limited and may not include people experienced with the specific – potentially novel – technologies featured in innovative medical devices;

✔ **Diversity** – It is hard to identify people from diverse disciplines with relevant prior knowledge at each of the many stages of device review; and

✔ **Complexity** – The regulatory review process lags behind the market in the ability to keep pace with advancements in technology. In addition, some devices require compliance with multiple sets of agency rules.

These challenges have real effects on the medical device industry and, potentially, public health. Long review times are bad for firms due to the potential for significant financial stress after large up-front investments, as well as due to the opportunity costs sacrificed during the review timeline.[5] Ineffective reviews are bad for the public because devices with the potential to kill or injure may be approved for widespread use. On the other hand, unnecessarily long review times for truly safe products are bad for the public, since under these circumstances life-saving products may take longer to reach patients.

As of 2012, it takes an average of 266 days for a device to pass through the PMA process.[6] The average PMA review time for a medical device increases markedly for unique devices – those with no predicate devices. Unique, innovative new devices are reviewed over the course of, on average, 18.1 months – 7.2 months longer than the approval time for the second such device.[7] Particularly regarding new and unique devices, extended review times are somewhat expected given the danger to public health that would arise from unsafe devices reaching market – and, indeed, longer approval timeframes currently correlate to fewer subsequent reports of adverse

4   Beth Simone Noveck, "If We Only Knew What We Know: Open Regulatory Review at the FDA," Yale Law & Policy Review 32, no. 2, 2014, https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDis-play&crawlid=1&doctype=cite&docid=32+Yale+L.+%26+Pol%27y+Rev.+545&srctype=smi&srcid=3B15&key=0fec-f1ae72fe78e33741b9b9143b335b.

5   Ariel Dora Stern, "Innovation under Regulatory Uncertainty: Evidence from Medical Technology," July 15, 2014, https://www.rotman.utoronto.ca/-/media/Files/Programs-and-Areas/Strategy/papers/JMP_Stern_Jan_2014.pdf.

6   FDA, "Improvements in Device Review: Results of CDRH's Plan of Action for Premarket Review of Devices," November 2012, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm329008.htm.

7   Ariel Dora Stern, "Innovation under Regulatory Uncertainty: Evidence from Medical Technology," July 15, 2014, https://www.rotman.utoronto.ca/-/media/Files/Programs-and-Areas/Strategy/papers/JMP_Stern_Jan_2014.pdf.

events.[8] HHS Profiles is rooted in the belief that better targeting using the expertise within the FDA and all of HHS for reviews could lead to faster, industry-benefitting reviews that do not sacrifice thoroughness or safety.

EXPERIMENTATION WITH HHS PROFILES

As part of a broader effort across HHS, the FDA's Office of Science and Engineering Laboratories (OSEL) at CDRH is launching an expert networking pilot project in response to these regulatory challenges. HHS Profiles is the agency's attempt to identify, quickly and intelligently, reviewers with specific areas of expertise for the pre-market review of medical devices. The FDA is partnering with the GovLab and its MacArthur Foundation Research Network on Opening Governance to develop and implement pilot projects to assess the effectiveness of using Profiles in this way.

Profiles imports and analyzes "white pages" (detailed contact) information, publications, and other data sources to create and maintain a complete, searchable library of web-based electronic CVs for experts within HHS. Profiles uses the Harvard Profiles Research Networking Software[9] platform developed by Harvard Medical School with support from the National Institutes of Health. The platform's User Group includes over 300 members from institutions around the world, such as the medical and biomedical faculties at Harvard, Penn State, Boston University, and UCSF.[10]

The HHS Profiles pilot program – which will be launched in 2016 with funding from the General Services Administration's The Great Pitch investment contest[11] – will evaluate several potential impacts of the introduction of this piece of expert networking software during the medical device review process. Within the target population of FDA and HHS personnel that Profiles is uploading into its database, it is possible to compare targeting participation with Profiles against status quo methods to understand the impact of general matching, and of matching based on academic degrees and publications. Does targeting on the basis of academic credentials have the downside of reaching those who are too busy to help and whose professional norms discourage such volunteer activity? Good academics may, for example, turn out to be bad participants because they are trained to contribute in ways that are unhelpful to regulators (i.e., academics used to writing long articles are often not all that useful to busy government professionals).[12]

The experimental rollout of the software will facilitate causal analysis of the software platform's

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8   Diana M. Zuckerman, Paul Brown, Steven E. Nissen, "Medical Device Recalls and the FDA Approval Process," February 2014, http://www.ncbi.nlm.nih.gov/pubmed/21321283.

9   http://profiles.catalyst.harvard.edu

10   http://profiles.catalyst.harvard.edu/?pg=community

11   https://figshare.com/articles/Developing_a_Model_for_Expert_Networking_Across_Federal_Government_The_HHS_Profiles_Pilot/2002110

12   Beth Simone Noveck, *Smart Citizens: Smarter State: The Technologies of Expertise and the Future of Governing*. Cambrigdge: Harvard University Press, 2015.

impact, including its effect on review panel composition, time needed for a panel to be convened, time required for a panel to review a new medical device, and subsequent safety outcomes for all products reviewed – e.g. product recalls and adverse event reports. The results of this pilot have the potential to inform and improve the process of regulatory review and will be relevant to the design of more effective regulatory review.

Moreover, adding empirical research into the rollout of HHS Profiles is a chance to experiment not simply between policies, but with how we make policy. The agile empirical manner in which the experimentation will occur is meant to help develop replicable methods for studying governance innovations in the wild, and accelerating the pace of research in government as a result.

ABOUT THE GOVLAB

The GovLab's mission is to improve people's lives by changing how we govern. Our goal is to strengthen the ability of institutions – including but not limited to governments – and people to work more openly, collaboratively, effectively and legitimately to make better decisions and solve public problems. For more information, please visit: *www.thegovlab.org*.

ABOUT SMARTER STATE

New tools—what GovLab calls technologies of expertise— are making it possible to match the supply of citizen expertise to the demand for it in government. Smarter State is a GovLab initiative to design and test how public decision-making could improve if institutions knew how to use the technologies of expertise to tap the wisdom of citizens' and civil servants.

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