Physician Entrepreneurs Are Key Contributors To New Medical Devices

Startup companies founded by physician entrepreneurs are an important source of patents used in developing innovative new medical devices, suggests a study in the May issue of Medical Care. The journal is published by Lippincott Williams & Wilkins, a part of Wolters Kluwer Health.

"Device manufacturers gain more from the patents of physician-founded firms than from those of non-physician-founded firms in their subsequent invention and innovation efforts," according to the study by Sheryl Winston Smith, PhD, and Andrew Sfekas, PhD, of the Fox School of Business at Temple University, Philadelphia. They raise concern that too-strict policies on financial relationships with physicians could hinder innovation in the medical device industry.

Doctors Make Key Contributions to New Medical Devices

The researchers analyzed a total 170 premarket approval applications (PMAs) filed by four major medical device companies between 1978 and 2007. The study also included data on patent applications from 119 startup companies—all of which had received investment dollars from the medical device industry. All four device makers had active corporate venture capital programs during the study period.

Using a sophisticated text-matching algorithm, Drs Smith and Sfekas assessed the information contributed by physician-founded startup companies versus non-physician-founded startups. The study focused on class III medical devices: the highest-risk classification, requiring significant testing to prove device safety and effectiveness.

The two groups of startups produced roughly the same number of patents. However, patents from physician-founded startup companies were cited more heavily in the PMAs, compared to those from non-physician-startups. "On average physician-founded companies account for eleven percent of the information in PMAs, compared to four percent from non-physician-founded companies," Drs Smith and Sfekas write.

Two-thirds of PMAs overlapped by at least ten percent with patents from physician-founded startups, compared to about one-fourth with patents from non-physician startups. Of PMAs with at least twenty percent information from external sources, about 80 percent included information from physician-founded startups versus 40 percent from non-physician-funded startups.

Could New Rules Hinder Device Innovation?

Facing intense pressure for constant innovation, the medical device industry relies

on corporate venture capital as a source of new ideas and patents. By assessing information overlap between PMAs and patents, the study algorithm helps in identifying which patents are more versus less important in developing successful new products. The results suggest that startup companies founded by physician entrepreneurs make uniquely important contributions to the development of new medical devices.

Historically, physicians have played a central role in the development process. Various types of financial relationships between physicians and medical device manufacturers are common, but are increasingly subject to policies regarding disclosure of potential conflicts of interest. These include the "sunshine provisions" of the Patient Protection and Affordable Care Act, under which drug and medical device manufacturers are required to report any financial relationships they have with physicians.

The new findings raise concerns that, if conflict of interest rules are too tight, they could have the unintended effect of slowing the pace of new advances in the medical device industry. Drs Smith and Sfekas write, "[R]estrictions on financial relationships between providers and industry, while potentially improving patients' trust, may result in reduced medical innovation if physicians found fewer startups or if incumbent firms reduce investments in physician-founded startups."

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