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NIH fails to disclose enough details about drug licensing, watchdog report finds

By Ed Silverman @Pharmalot

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Amid increasing debate over the cost of prescription drugs, a federal watchdog

agency found the National Institutes of Health does not consider whether a medicine it discovered and licensed to a pharmaceutical company may later be affordable, and also fails to provide enough information about its licensing activities to assess patient access.

The failure to consider the impact that licensing has on public health, especially at a time when a growing number of Americans say they cannot afford their medicines, prompted the Government Accountability Office to recommend that the NIH do a better job of disclosing licensing data and pay more attention to the potential for anti-competitive practices that affect drug pricing.

"The level of information that NIH publicly reports at present does not allow researchers or members of the public to evaluate the effectiveness of licensing, an important element of NIH's broader intellectual property management practices," the GAO wrote in a lengthy review of NIH licensing practices that was requested by several lawmakers earlier this year.

The implications are far-reaching. Since 1980, research conducted by the Department of Health and Human Services, which oversees the NIH, generated more than 4,400 U.S. patents that owned by the federal government and 32 licenses that contributed to the development of 34 drugs that were ultimately approved by the Food and Drug Administration.

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Although the GAO acknowledged this represents a small portion of drugs approved by FDA, the medicines included new treatments for such life-threatening diseases as cancer and HIV, while generating "substantial revenues" for the pharmaceutical industry. Yet the NIH does not report which of its patents are licensed or release metrics to understand the affect these deals have on the public.

The GAO analyzed 94 patents licensed by NIH that led to the development of those 34 drugs and found 45 patents involved an invention related to an active pharmaceutical ingredient of a drug and 47 were related to a method of using or producing a drug.

"Information of this kind is necessary for a better understanding of NIH's role in drug development and, more broadly, of the impact of various facets of NIH's management of its intellectual property on public health," the GAO concluded.

The findings were released as controversy brews over the cost of medicines that are discovered, at least in part, by various NIH agencies that are funded by U.S. taxpayer dollars. Over the past few years, the NIH has increasingly been pushed by a growing number of lawmakers, academics, and consumer groups to consider patient affordability for medicines that emerge from government-financed work.

Generally, the NIH has failed to be more assertive about ensuring government-funded research can provide sufficient access to the public, according to the report. The GAO cited an instance in 2003, when the Federal Trade Commission found Bristol Myers Squibb (BMY) used anti-competitive practices to thwart lower-cost generic competition to the Taxol cancer drug that was licensed from the government.

In a rare instance, the federal government last year filed a lawsuit accusing Gilead Sciences (GILD) of infringing on patents for an HIV prevention pill and unfairly reaping hundreds of millions of dollars from research funded by taxpayers. In that case, however, a licensing deal was not yet in place and, in fact, the two sides had spent three years trying to reach an agreement based on the patents.

For its part, the NIH contended that its mandate does not encompass drug pricing or affordability and, in any event, its staff lacks the expertise to address this topic. NIH officials also told the GAO that there are concerns that pricing stipulations might prompt pharmaceutical companies to shy away from reaching deals and

hamper innovation, which is why the NIH removed such language from contracts in 1995. As far as anti-trust issues are concerned, the NIH argued other federal agencies can better tackle this.

To remedy the problems, the GAO suggested the NIH incorporate language in its licensing deals to prevent drug makers from taking steps that could preclude competition to medicines that were discovered with taxpayer money. The watchdog also recommended the NIH take steps to be more transparent by disclosing more information about licenses and make it easily accessible.

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Although the NIH agreed with the recommendations, reaction was mixed.

Two lawmakers that want the NIH to strengthen publicly-owned intellectual property praised the GAO report for shining a light on the issue and detailing circumstances in which NIH officials should have been doing a better job. U.S. Sen. Debbie Stabenow (D-Mi.) noted in a statement that there is "more work to be done," but expressed satisfaction that the NIH agreed to increase transparency.

One academic, meanwhile, was dubious. In an e-mail, Jacob Sherkow, a law professor at the University of Illinois at Urbana-Champaign who specializes in patents and life sciences, wrote us that the report has the potential to solve some concerns if the NIH does make licensing efforts more transparent.

"With that said, whether the recommendations in the report are strong enough to effect actual change remain uncertain," he continued. Why? He explained that including language to require drug companies avoid anti-competitive behavior is "nothing licensees couldn't do in theory already. Simply stating so in the license ain't gonna do much."

As for disclosing more licensing data, Sherkow indicated such a move could be meaningful to the public if information is placed in a searchable format. "I wish the report was more forceful about its recommendations concerning data transparency, but even this little bit is better than nothing. In data, like life, we shouldn't let the perfect be the enemy of the good."

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Another expert was also concerned the GAO recommendations do not go far enough.

For instance, the GAO noted NIH licensing agreements do not include language in a federal law known as the Bayh-Dole Act, which allows the NIH to "march in" and require a drug maker to license its patent to another party in order to "alleviate health and safety needs which are not being reasonably satisfied," or when the benefits of a product, such as a medicine, are not available on "reasonable terms."

But the GAO did not push this point.

For this reason, Brook Baker, a professor at Northeastern University School of Law and a senior policy analyst for the Health GAP advocacy group, called the recommendations "limited… the GAO report does not concentrate on central problems in oversight of government licensing decisions – when exclusivity is given, how long it lasts, how public investments should be reflected in pricing and distribution practices, and control over unreasonable pricing."

About the Author Reprints

Ed Silverman

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com
@Pharmalot

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