NIAID Evaluates Population-Wide Testing, Early Treatment for HIV Prevention

A study in South Africa and Zambia will assess whether house-to-house voluntary HIV testing and prompt treatment of HIV infection, along with other proven HIV prevention measures, can substantially reduce the number of new HIV infections across communities.

The trial, Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART), or HPTN 071, is sponsored and co-funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH.

The PopART study will build on the results of the landmark, NIAID-funded HPTN 052 trial, which found that HIV-infected individuals who start treatment early, when their immune systems are relatively healthy, dramatically reduce the risk of transmitting the virus to their heterosexual partners.

"Through this new study, we aim to learn whether the treatment of HIV-infected individuals as a form of HIV prevention, an approach previously tested in roughly 1,800 heterosexual couples where one partner was infected, will be just as effective when implemented across an entire adult population," said NIAID Director Anthony S. Fauci, M.D. "The study also will tell us whether this method of delivering population-wide HIV treatment as prevention is feasible and cost-effective."

"Mathematical models indicate that if a high proportion of a population can be tested for HIV, and those found to be infected are offered treatment right away, then the rate of new HIV infections could decrease substantially over time," said Dr. Richard Hayes, D.Sc. "The PopART study is assessing whether this approach works and whether the benefits outweigh the costs—information that could help guide public health policy."

The PopART trial will involve 21 communities in South Africa and Zambia with a total population of 1.2 million. The study team has randomly assigned each community to one of three groups. One group of communities will receive the HIV prevention package along with the opportunity for HIV-infected individuals to begin treatment as soon as they test positive for the virus. The second group will receive the same HIV prevention package, and infected individuals will be offered treatment at the stage of infection recommended by their country’s HIV treatment guidelines. The third group will serve as a control and will receive existing HIV prevention and testing services along with HIV care and treatment according to current national guidelines for their country.

The study team will measure the impact of the two HIV prevention packages by determining the number of new HIV infections among a representative sample of 52,500 adults drawn from the 21 study communities and followed for three years. The study is expected to end in 2019.

For more information on this study, click here.
On October 18, the Anti-Infective Drugs Advisory Committee met to discuss the safety and effectiveness of new drug application (NDA) 204684, miltefosine capsules, submitted by Paladin Therapeutics, Inc., for the proposed indication of treatment of patients with visceral (involving internal organs), mucosal (involving areas such as inside the mouth and nose), and cutaneous (involving the skin) leishmaniasis.

CDER provided a live webcast of the October 18 meeting of the Anti-Infective Drugs Advisory Committee. For more information on this meeting, include an agenda and briefing materials, please click here.

On October 24, the Antiviral Drugs Advisory Committee met to discuss a new drug application (NDA) 205123, simeprevir (a hepatitis C virus protease inhibitor), manufactured by Janssen Pharmaceutical Co., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin (two medicines approved to treat chronic hepatitis C) in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve or who have failed previous interferon therapy (pegylated or non-pegylated) with or without ribavirin. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.

On October 25, the Committee met to discuss new drug application (NDA) 204671, sofosbuvir (an NS5B polymerase inhibitor), manufactured by Gilead Sciences, Inc., with a proposed indication for the treatment of chronic hepatitis C infection, in combination with other agents in adult patients with genotypes 1 to 6 and/or adult patients awaiting liver transplantation.

For more information on these meetings, including transcripts and briefing materials, please click here.
**PATIENT ORGANIZATION EVENTS**

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<td>2013 Clinical Vaccinology Course</td>
<td>11th International Congress on AIDS in Asia and the Pacific</td>
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SEC FINALIZES JOBS ACT REGULATION D RULEMAKING

The SEC has finalized its rules implementing the Regulation D reforms mandated by the JOBS Act. As of September 23, companies are now able to use general solicitation to advertise to investors when conducting an offering under Rule 506 of SEC Regulation D, as specified by the law. Rule 506 is a popular capital formation outlet that allows issuers to raise an unlimited amount of capital from accredited investors, and the JOBS Act reforms to the process should further increase its utility.

The JOBS Act directed the SEC to lift the ban on general solicitation for offerings conducted under Rule 506, provided that issuers A.) sell securities only to accredited investors and B.) take reasonable steps to verify that all purchasers in an offering are accredited. The SEC implemented these reforms by creating a new Rule 506(c) that allows general solicitation in offerings to accredited investors.

BIO has prepared an overview of the new opportunities available under Rule 506(c) and the requirements for issuers wishing to take advantage of them. Please click here to access this FAQ document. This service is a non-legal policy overview of the statute, designed to help keep you informed on the new rules. It is not intended to, and does not, constitute legal advice – please consult your own legal team if you are considering an offering or have any specific questions about the statute or relevant SEC regulations.

BIO COMMENTS ON SEC DISCLOSURES PROPOSAL

The SEC has issued a proposed rule that would enhance disclosures related to offerings conducted under Rule 506(b) and Rule 506(c) of SEC Regulation D. This proposal would make certain changes to Form D requiring more information from issuers. It would also update the disclosure requirements to reflect the ability of issuers to conduct general solicitation under Rule 506(c) and the requirement that they take reasonable steps to verify that their purchasers are accredited investors.

BIO provided feedback to the SEC on this proposed rule, expressing concern that costly disclosure requirements could serve as a roadblock to growing biotech companies considering a Rule 506 offering. To read BIO’s comment letter, please click here.

CSBI ANNOUNCES TAX PROPOSALS WOULD INCREASE INVESTMENT BY $20.6 BILLION—CREATE 623,000 JOBS

The Coalition of Small Business Innovators (CSBI) released the results of a study conducted by Ernst & Young that examines the economic impact of three legislative proposals designed to help small R&D-intensive start-up companies and other small businesses better utilize existing tax provisions, and incentivize investment in small business innovation. If enacted together, the three proposals would increase total investment by $20.6 billion and result in an estimated 623,000 jobs when indirect and induced economic effects are included.

The proposals also would have a significant impact on investment and employment when considered separately:

- The R&D partnership structures proposal reforming Section 469 passive activity loss rules would increase investment by an estimated $10.3 billion per year, resulting in 156,000 additional jobs at affected companies.
- The reform of Section 382 to allow small companies to retain their net operating losses generated by R&D expenditures would increase investment by a total of $5.5 billion per year, resulting in 85,000 additional jobs at affected companies.
- The extension and expansion of the qualified small business stock provision in Section 1202 would increase investment by $3.6 billion, resulting in 355,000 additional jobs at affected companies.

To learn more about the proposals and the Coalition’s advocacy priorities, click here.

For more information on the Coalition of Small Business Innovators, please visit smallbusinessinnovators.org or to access the full study click here. The Coalition also has Facebook and Twitter accounts.
BIO BOARD MEMBER TESTIFIES ON JOBS ACT

On July 10, BIO Board member Ken Moch, President and CEO of Chimerix, provided testimony before the House Subcommittee on Capital Markets on the importance of a functioning public market to biotech capital formation. The hearing, titled “Reducing Barriers to Capital Formation,” focused on policy proposals that could improve liquidity and reduce regulatory barriers that growing companies face after an IPO. Members also expressed interest in the recent successes of the JOBS Act, which has spurred more than 40 public offerings in the biotech industry.

Chimerix went public using provisions in the JOBS Act, and Mr. Moch shared his experience as a CEO complying with new rules. In particular, he praised the testing-the-waters and confidential filing provisions, saying that they were extremely beneficial to Chimerix’s offering. Additionally, he expressed optimism about the exemption from Sarbanes-Oxley (SOX) Section 404(b) compliance provided by the JOBS Act, noting that pre-revenue biotechs are often forced to divert funds from the lab in order to comply with SOX.

During the hearing, Mr. Moch voiced support for Congressional efforts to enact market structure reform to improve the trading environment for small public companies. He specifically advocated for the Fostering Innovation Act (H.R. 2629) and the Audit Integrity and Job Protection Act (H.R. 1564). He also emphasized the importance of reforms to the existing tick size regime and questioned the efficacy of XBRL compliance for growing innovators.

To read Mr. Moch’s testimony in full, please click here. BIO is continuing to advocate for market structure reform legislation to build on the success of the JOBS Act and ensure that the public markets remain a viable fundraising outlet for biotech innovators.

REP. FITZPATRICK INTRODUCES FOSTERING INNOVATION ACT

On July 10, Rep. Michael Fitzpatrick (R-PA) introduced H.R. 2629, the Fostering Innovation Act. H.R. 2629 will reduce regulatory burdens on small public companies, allowing emerging biotech companies to focus on groundbreaking research rather than spending capital on bureaucratic red tape.

Under current SEC rules, public companies are grouped by size to determine compliance requirements. The smallest group, called non-accelerated filers, is capped at companies with a public float of no more than $75 million; these small businesses have fewer regulatory burdens, including an exemption from Sarbanes-Oxley (SOX) Section 404(b). The Fostering Innovation Act will amend the filing status classifications in SEC Rule 12b-2 to allow companies with public floats below $250 million or revenues below $100 million to qualify as non-accelerated filers.

Rep. Fitzpatrick’s legislation will group companies with common characteristics together, giving the SEC more accurate filing classifications and providing important regulatory relief to startups working on cutting-edge scientific breakthroughs. This change will reduce their regulatory burden and, for growing biotech innovators, allow them to spend valuable innovation capital on breakthrough research.

To learn more about the Fostering Innovation Act, please click here.

ALLERGY/INFECTIOUS DISEASE/ANTIVIRAL-FOCUSED LEGISLATION

H.R. 1792—Infectious Disease Reporting Act
This bill would direct the Secretary of Veterans Affairs to report each case of reportable infectious disease that occurs at a medical facility of the Dept. of Veterans Affairs to the appropriate state entity.

Sponsor: Rep. Mike Coffman (CO-6)
Status: Referred to the House Committee on Veterans’ Affairs

S. 330—HIV Organ Policy Equity Act
This bill would amend the Public Health Service Act to authorize the Organ Procurement and Transplantation Network to adopt standards for the acquisition and transportation of organs infected with HIV.

Sponsor: Sen. Barbara Boxer (CA)
Status: Referred to Subcommittee on Crime, Terrorism, Homeland Security, and Investigations
BIO Meets and Conferences

BIO IPCC Conference
November 6-8, 2013
Washington, DC

BIO Convention in China
November 11-13, 2013
Beijing, China

BIO CEO & Investor Conference
February 10-11, 2014
New York, New York

BIO International Conference
April 8-9, 2014
Tokyo, Japan

BIO International Convention
June 24-26, 2014
San Diego, California

For more about BIO events, please click here.

BIO Publishes JOBS Act Deconstructed Blog Post Series

More than 40 biotech companies have gone public using provisions made available to emerging growth companies through the JOBS Act. BIOtechNOW’s “JOBS Act Deconstructed” series explores why it has had such an impact on biotech offerings and how emerging companies can leverage the new law to their best advantage.

The blog post series, published earlier this fall, highlights the testing-the-waters, confidential filing, and regulatory relief provisions in the IPO On-Ramp created by the JOBS Act. There is an additional non-IPO post dedicated to the SEC’s recent rulemaking action implementing the reforms to Regulation D in the new law. To read the “JOBS Act Deconstructed” series at BIOtechNOW, please click here.

Research!America Joins the Coalition of Small Business Innovators

Research!America, the nation’s largest nonprofit public education and advocacy alliance working to make research to improve health a high national priority, announced that it joined the Coalition of Small Business Innovators (CSBI). CSBI is a national, non-partisan coalition of organizations dedicated to stimulating sustained, private investment in small, highly innovative companies focusing on the development of new technologies.

The Coalition believes that, through the tax code, Congress and the Administration should enact policies that promote greater private investment in small business research-intensive innovation in order to maintain America’s global competitiveness, sustain and create American jobs, and incentivize investments in the United States.

CSBI supports a U.S. tax code that recognizes innovation as a crucial part of the 21st century American economy and believes that, by itself, a lower corporate tax rate will not support growth and innovation in America’s small businesses, many of which are pre-revenue. The Coalition advocates for policymakers to both lower the corporate rate and to specifically promote innovative pre-revenue research-intensive businesses though incentives that spur private investment, encouraging other companies, individuals, and funds to invest in small companies and support their research.

To learn more about CSBI or read Research!America’s press release announcing its membership, please visit smallbusinessinnovators.org or click here.