Federal Financial Analytics, Inc.

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August 21, 2018

Secretariat to the Financial Stability Board
Bank for International Settlements
Centralbahnplatz 2
CH-4002 Basel, Switzerland

RE: Evaluation of the effects of financial regulatory reforms on infrastructure finance

Dear Sir or Madam:

This comment responds to the Financial Stability Board (FSB) request for views on ways to advance global infrastructure finance without increasing financial-stability risk. I write as managing partner of Federal Financial Analytics, Inc., a consultancy focused on financial-policy matters, speaking only for myself and not for any clients. No private-sector client has reviewed, advised, or requested this letter. In it, I urge the FSB to expand the definition of "infrastructure" in its final report to the Group of Twenty (G20) to include biomedical research that has advanced past the early stages of research to show promise as a potential treatment or cure but for which private-sector funding from entities such as venture-capital firms remains all too scarce.

Although the consultation includes "social-infrastructure" financing within the scope of its analysis, its phrasing suggests that this covers only physical infrastructure (i.e., hospital construction). While physical infrastructure is of course vital to social welfare and macroeconomic growth, there is no greater engine for individual success and national prosperity than a healthy, fully-abled population that does not need a hospital. This will come not only from improved healthcare delivery but also from treatments and cures for once-incurable diseases and disabilities. Speeding the development of these treatments and cures is therefore a particularly critical policy objective that should be fully included in the scope of infrastructure projects benefiting from FSB attention and resulting regulatory reforms.

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In this letter, I will make it clear why "translational" biomedical research is suitable for private-sector funding and lay out the social-welfare, macroeconomic, and financial-stability benefits that would ensue from faster treatments and cures. I will outline one such effort in the U.S. akin to the guarantees described in the consultation for other infrastructure and reference work in many nations to promote translational research. I will then conclude by reiterating that the FSB should not allow an unduly narrow definition of the infrastructure projects eligible for favored regulatory treatment to influence credit-allocation decisions in such a way as to create inadvertent inequality effects.

RECOMMENDATION: The FSB should avoid a rigid definition of the infrastructure eligible for special asset-class or other regulatory treatment by expanding it to include all long-term projects requiring private finance that suffer from capital shortages to the detriment of social welfare and macroeconomic growth as determined by national authorities under applicable law and rule. The definition should be constrained only to prevent high-risk, speculative projects in order to ensure safety and soundness, prevent implicit taxpayer recourse, and avoid regulatory arbitrage. In the event the FSB is not now able to expand its definition, the existing discussion of eligible infrastructure in the final report should clarify that loans supporting biomedical translational research are included within the construct of social-welfare infrastructure.

Translational Biomedical Infrastructure

Just as a bridge spans a valley between two roads, joining them to the greater prosperity of the economies on either side, so translational biomedical research bridges the gap between basic research and the end-stage clinical trials that bring treatments and cures to patient populations. Basic research – which is almost always funded by government and philanthropic resources – is work at the molecular level, in mouse trials, and even through computer modeling to identify ways to prevent, treat, and cure disease and disability. It is usually very expensive and requires years of diligent research prior to identification of promising projects likely to be both effective and safe. However, once a project moves into its pre-clinical research phase (e.g., identifying patient populations) and then commences early-stage trials with patients, additional funding is needed for several years of additional work. Only once these early-stage trials are complete is a prevention, treatment, or cure ready for the end-stage trials often funded by venture-capital firms or large biopharmaceutical companies.

The long years in which deserving research lacks funding and the abundance of promising projects that never make it to end-stage evaluation cause unnecessary suffering, premature death, family tragedy, and enormous direct and indirect economic losses. Reflecting this,

patients in the U.S. and other nations have pressed to be able to try unproven or even dangerous drugs in the hope of curing terminal or profoundly debilitating diseases. Such patients and their families take enormous risks which would be dramatically reduced if the time from successful basic research to authorized treatment and cure were accelerated.

It is therefore essential to develop financial instruments that bridge the valley – often called the valley of death by biomedical researchers – between promising basic research and actual treatments and cures. The extent to which major advanced, market-based economies are currently addressing this need through programs supporting translational biomedical research is hard to quantify due to blurred distinctions between public and private finance in some economies, the differences in how the start and end points of translational medicine are defined, and the mix of direct research and indirect support considered "translational" by national and regional governments. Certain public-sector entities are also active in this space, further complicating data analysis.

Because of the long-term nature of translational research, the complexities of identifying promising projects entering the translational phase, and the inherent risk in biomedical research, there are few private financial instruments supporting translational research outside the realm of "venture philanthropy." Unless investments are backed by a sovereign guarantee, matching funds, or other types of assistance, many investors will opt instead for quicker, easier money even at a loss in overall returns. However, as with physical infrastructure, long-term, risk-averse investors such as insurance companies and pension funds are ideally suited to invest in biomedical research infrastructure when structured into assets consolidating risk across an array of projects likely to provide return on capital.

Current impediments to such funding stem from the same market and regulatory obstacles the FSB has identified for physical infrastructure such as information asymmetry due to project complexity and high holding costs over the life of a project. Some of these impediments are also the result of regulatory requirements that so undermine risk-adjusted return on capital as to render the private sector unwilling to supply capital, despite the likelihood of long-term return on investment comparable to other investment options.

Defining Translational Biomedical Projects for the Infrastructure Asset Class

As with physical infrastructure, public agencies are well-suited to determine which translational biomedical projects are likely to bridge the gulf between basic research and end-stage trials. However, legislation pending in the United States to create "Eye Bonds" to speed treatments and cures for blindness and severe vision impairment would do so.

H.R. 6421 relies on the National Eye Institute (NEI) to pick eligible projects. The NEI is an institute within the U.S. Government's National Institutes of Health (NIH) that funds the majority of U.S. basic research for vision disorders. A private-sector underwriter would structure investment vehicles composed of NEI-approved projects across the spectrum of research to ensure portfolio diversification and cash-flow matched to bond maturity. Up to $1 billion over five years of these Eye Bonds could be issued as part of a pilot program designed to test this approach. A federal guarantee would back up to fifty percent (50%) of the principal amount of each bond, with cash flows held in escrow by the Treasury Department until the balance of the account ensures full protection for the U.S. taxpayer.

Other nations already have programs that include many of the characteristics of these "Eye Bonds," offering them out of the conviction that translational biomedical research is an essential form of social-welfare infrastructure.

Recommendation

Consistent with broader plans to create an asset class including certain physical structures that would be eligible for special treatment under applicable national standards, translational biomedical research efforts that share similar characteristics should be included in the definition of "infrastructure" for purposes of this asset class. Eligible projects should include those selected by a national authority for scientific merit that fund research and development in the translational space as each nation chooses to define it. Additionally, eligible projects should be those with a sufficient number of diverse investments included in each financial instrument, a deep public-sector guarantee, or other terms and conditions (e.g., collateral and risk tranching) sufficient to reduce risk over the life of the instrument. Such measures should seek reasonably to mitigate the probability of default and the loss given default consistent with a risk weighting of no more than fifty percent (50%) under the Basel Committee's standardized approach or comparable regulations governing the insurance industry and pension funds. A 50% risk weighting is appropriate for projects that meet these conditions because it is comparable to weightings for higher-risk instruments (e.g., higher loan-to-value mortgages) under the Basel rules. No data now permit a precise calculation regarding accurate weightings because of the diverse nature of these instruments, and any such risk weighting should be considered provisional pending additional research. However, the demonstrable social-welfare benefits of speeding treatments and cures and the relatively small size of translational biomedical research in national financial markets warrant a conservative rating of 50% or more. All portions of translational financial instruments backed by a full-faith-and-credit sovereign guarantee should receive the risk weighting, treatment under

applicable liquidity regulations, and other regulatory benefits generally accorded to financial instruments with comparable sovereign backstops.

Sincerely,

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