

Frank J. Sasinowski



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Frank J. Sasinowski, M.S., M.P.H., J.D., assists sponsors in developing new medicines and has helped secure FDA approval for hundreds of new drugs including more than 45 new molecular entities, often for serious and/or rare diseases. Frank joined FDA in 1983 as regulatory counsel in the Center for Drugs and Biologics, where he was key to implementing both the 1983 Orphan Drug law and the 1984 Hatch-Waxman law. Frank twice received the FDA Award of Merit. In 1987, he left the FDA as Deputy Director of the health policy staff in the Commissioner's office and joined this firm.

In May 2013, the National Organization for Rare Disorders (NORD), which represents the 30 million Americans with rare diseases, awarded Frank its first ever NORD Lifetime Achievement Award. In 2000, Frank was elected to NORD's Board of Directors, where he has served as Chair and as Vice Chair, and where he remains on the Board today. NORD had, in 2000, previously honored Frank with its Humanitarian Award.

In its March 2012 issue, the Drug Information Journal published Frank's seminal analysis on therapies for rare disorders: "Quantum of Effectiveness Evidence in FDA's Approval of Orphan Drugs: Cataloguing FDA's Flexibility in Regulating Therapies for Persons with Rare Disorders." In October 2012, President Obama recognized Frank's contributions to the President's Council of Advisors on Science and Technology (PCAST) report, "Propelling Innovation in Drug Discovery, Development and Evaluation."

Frank has also served on the Board of Directors of the United States Pharmacopeia (USP). For 7 years, Frank served on the Board of Directors, including as Vice Chair, of the Catholic Medical Mission Board (CMMB), a 100 year old international health Non-Governmental Organization (NGO) that last year provided over a billion dollars worth of health products and services to those in need in less developed nations. CMMB has been a leader in the PEPFAR program in Africa and a key health care provider in Haiti and Central and South America. Frank currently is a charter member of the Advisory Council of Global Camps Africa, and he also serves as a volunteer Chaplain at the Northern Virginia Mental Health Institute in Fairfax, VA. Frank currently serves on the Board of Directors of the Shalem Institute for Spiritual Formation.

Frank has been on the Board of Directors of biotechnology companies. Frank has been Chair of the Food and Nutrition Section of the American Public Health Association (APHA) and has taught health law at American University. Frank holds a Masters of Science in nutritional sciences and a Masters of Public Health from the University of California at Berkeley, a Bachelor of Science in biological sciences and genetics from Cornell University, and a Juris Doctorate from the Georgetown University Law Center. He is admitted to practice in the District of Columbia.

Committee on Energy and Commerce
U.S. House of Representatives
 Witness Disclosure Requirement - "Truth in Testimony"
 Required by House Rule XI, Clause 2(g)

1. Your Name: Frank J. Sasinowski		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No X
3. Are you testifying on behalf of an entity that is not a government entity?	Yes X	No
4. Other than yourself, please list which entity or entities you are representing: Hyman, Phelps & McNamara, P.C. National Organization of Rare Disorders		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011: N/A		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing: N/A		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes	No X
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed: N/A		
9. Please attach your curriculum vitae to your completed disclosure form. <i>Attached</i>		

Signature



Date: *May 16, 2014*