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ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION HEARING ON:

"FOSTERING THE COMPETITIVE EDGE: EXAMINING THE EFFECT OF FEDERAL POLICIES ON COMPETITION, INNOVATION, AND JOB GROWTH"

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Chairman Quayle and Ranking Member Edwards, Members of the Committee, it is my privilege to provide testimony today on the crucial issue of ensuring we foster biomedical innovation in the United States. My name is Ron Cohen and I am the President, CEO, and founder of Acorda Therapeutics, Inc. Prior to founding Acorda, I was a principal in Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation. I have over 25 years of experience in the biotechnology industry and currently serve as a member of the Columbia-Presbyterian Health Sciences Advisory Council. I am a recipient of the Ernst & Young Entrepreneur of the Year Award for the New York Metropolitan Region and am an inductee of the National Spinal Cord Injury Association's "Spinal Cord Injury Hall of Fame." I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO), where I serve as Chairman of the Emerging Companies Section Governing Board. BIO represents more than 1,100 companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

Acorda is a small biotechnology company located in Hawthorne, New York. I founded the company in 1995 with one mission – to develop therapies that could restore neurological function and improve the lives of people with multiple sclerosis (MS), spinal cord injury (SCI), and other disorders of the nervous system. We launched our first FDA-approved medication,

Zanaflex Capsules, in 2005; Zanaflex is a drug that helps with the management of spasticity. In 2010 we obtained FDA approval for Ampyra, a drug that improves walking in people with MS; the majority of patients afflicted with this disease experience impairment in their ability to walk. In addition to Ampyra and Zanaflex, we are working on four treatments that we hope will protect nerves in the spinal cord or brain from the consequences of traumatic injury or stroke, regenerate neural connections in existing injuries, and address damage to or loss of myelin (the insulating layer of cells that surround nerve fibers).

Our company went public in 2006 and today we have 330 employees who are working on our pipeline of innovative medicines that could be transformative in the lives of patients afflicted with neurological diseases. Although the company has matured and many of our employees are based at our headquarters in Hawthorne, NY, we have remained true to our origins as a collaborative enterprise – both within the company and with external partners in academia and industry, with whom we share a sense of mission. This unusually high level of teamwork has contributed substantially to our ability to innovate successfully, from product identification to preclinical, clinical, and commercial development.

I am here today to talk about the state of the biotechnology industry in the United States and to discuss polices that have been enacted or are currently being considered by Congress that would ensure we have a robust biotech industry in the U.S. for the foreseeable future.

THE UNITED STATES BIOTECHNOLOGY INDUSTRY: IMPORTANCE OF DEVELOPING POLICIES THAT FOSTER INNOVATION

It is imperative that we have policies that encourage research and development of the next generation of treatments and cures. America has developed more cures and breakthrough medicines than any other country and is home to over 2,500 biotech companies. However, this position cannot be sustained without a concerted policy focus on supporting and incentivizing the next frontier of biomedical discoveries, treatments, and cures. Recently there have been a few headlines touting increased investment in the biomedical field. Unfortunately, these headlines oversimplify the actual state of affairs. The National Venture Capital Association (NVCA) recently released their fourth quarter 2011 numbers for venture financing of

biotechnology in the U.S. While the numbers showed an overall 18% increase in investment from 2010 to 2011, this is misleading with regard to the situation that most small, innovative biotechnology companies are facing.[1] The 2011 investment in biotechnology is actually 12% lower than the peak we saw in 2007, and the total number of venture financing deals was down 8% since 2010. Most importantly, especially to small innovative companies, the number of venture-funded early-stage companies fell by 19%.[2] The number of investments moving away from early-stage innovative projects is an alarming trend that has been growing over the past few years – in fact, the number of first-time financings for life sciences companies is at its lowest level since 1996.[3]

Over the past year we have seen several long-time investment funds announce they will no longer be investing in the medical science sectors. An October 2011 survey conducted by the NVCA and MedIC showed that 40% of venture capitalists expect to decrease investment in biopharma over the next three years, three times as many as the number who expect to increase. This same survey showed that 61% cited regulatory challenges at the FDA as the main reason for reducing investments.[4] This is not entirely surprising given that the time and costs to develop a novel drug have continued to increase over the past decade. In fact, today, it requires an average of 10 to 15 years and $800 million to over $1 billion to develop a new drug, and that cost is continuing to increase at a disturbing rate.[5,6,7,8] In part this increase in cost can be attributed to the increased complexity of regulatory requirements. For example, between 1999 and 2005 the average length of clinical trials grew by 70%.[9] The combination of these increased costs,

[1] NVCA/PWC MoneyTree Report: Q4 2011. Data provided by Thomson Reuters.
[2] "Venture Capital increases in 2011, but…" Inside BIO Industry Analysis. 24 January 2012. http://www.biotech-now.org/business-and-investments/inside-bio-ia/2012/01/vc2011
[3] NVCA/PWC MoneyTree Report: Q4 2011. Data provided by Thomson Reuters.
[4] NVCA/MedIC Survey. Vital Signs. October 2011.
[5] "Returns to R&D on New Drug Introductions in the 1980s." Journal of Health Economics 13, no. 4 (1994): 383-406
[6] H.G. Grabowski, J. Vernon, and J.A. DiMasi, "Returns on Research and Development for 1990s New Drug Introductions," Pharmacoeconomics 20, supp. 3 (2002): 11–29
[7] J. Dimasi and H Grabowski J "The Cost of Biopharmaceutical R&D: is Biotech Different?" Managerial and Decision Economics no 28 (2007): 469–79
[8] Munos, Bernard. "Lessons from 60 years of pharmaceutical innovation." *Nature Reviews Drug Discovery* 8, 959-968 (December 2009).
[9] Tufts Center for the Study of Drug Development. 2008. "Growing Protocol Design Complexity Stresses Investigators, Volunteers." Impact Report. 10.1.

regulatory uncertainty, and lack of fiscal incentives is causing investors to move their funds to lower risk propositions and/or overseas.

We are facing unprecedented competition from around the globe to be the leader in biomedical research. In 2008, China pledged to invest $12 billion in drug development,[10] and in 2011, the Chinese government named biotechnology as one of seven industries that will receive $1.7 trillion in government funding over the next five years.[11] The European Union's Innovative Medicines Initiative is pumping $2.65 billion into Europe's biopharma industry[12] and India's Bioconnect initiative has funded over 200 new biopharma projects.[13] While America has developed more cures and breakthrough medicines than any other country, this is not a position that will be sustained without continued investment and policies focused on supporting and incentivizing the next generation of biomedical discoveries, treatments, and cures.

The U.S. biotechnology industry is poised to be a major driver in an innovation-driven economy and we offer real solutions to our most pressing health care needs: curing disease, reducing costs, increasing quality, and ensuring that people enjoy not only longer lives, but better and more productive lives. Our biotech companies provide high-wage jobs at both public research institutions and in the biotech companies that typically locate near centers of academic research. The indirect effects of increased research funding on the regional economy are significant. For example, sponsored biomedical research directly generates jobs in the host institutions, and indirect and induced job creation in the region amounts to additional job growth. In fact, the nation's 1.42 million bioscience jobs support an additional 6.6 million jobs in the United States, resulting in a total employment impact of over 8 million jobs.[14]

It is also critical that in an environment of budgetary constraint we do not lose sight of the fact that innovative medicines can actually help reduce healthcare costs. For example, Medicare is expected to spend over $100 billion in 2012 caring for individuals suffering from Alzheimer's

[10] Daverman, Richard. "China Launches 'Mega Program' to Fund Drug Development." ChinaBio Today. 9 November 2008. http://www.chinabiotoday.com/articles/20081109
[11] Buckley, Chris. "China to invest US$1.7 trillion over 5 years in 'strategic sectors': US official." The China Post. 23 November 2011. http://www.chinapost.com.tw/business/asia-china/2011/11/23/323724/China-to.htm
[12] Hodgson, John. "€2 billion IMI launched with European pharma." *Nature Biotechnology 26*, 717-718 (2008).
[13] Dandekar, Vikas. "India Draws Lessons From China To Help Foster Biotech Industry." PharmAsia News. 7 February 2012.
[14] Battelle/BIO State Bioscience Initiatives 2010. Battelle Technology Partnership Practice, May 2010.

disease.[15] Delaying the onset of Alzheimer's by just five years would save $50 billion per year.[16] A similar calculus applies to numerous chronic, debilitating diseases, including heart failure, kidney disease, diabetes, and arthritis. By 2030, almost one out of every five Americans – some 72 million people – will be 65 years or older. And as almost 75 cents of every health care dollar spent is for taking care of individuals suffering from a chronic disease, it could not be clearer that we have a national imperative to find new solutions in how we treat patients and diseases.

In order to fully realize these potential benefits we must have a policy environment that fosters innovation. There are five policy areas necessary to enable us to deliver the next frontier of medical breakthroughs: 1) protection of intellectual property – to protect the main driver in securing private sector investment; 2) funding for basic research and an effective technology transfer system – to ensure that the latest scientific discoveries are able to be developed by industry and made available to patients; 3) funding opportunities for early-stage clinical research and development – to ensure that early-stage discoveries are fostered in order to encourage private sector investment; 4) tax and financial services policies that encourage investment and support biotechnology companies; and 5) a well-funded FDA with transparent and consistent regulatory processes that enable the timely, efficient, and predictable review of innovative medicines and allow for the use of modern scientific tools and methodologies that make the drug development processes more efficient. My testimony today will focus mainly on economic and regulatory proposals that would serve to preserve our position as global leaders in biomedical innovation.

INTELLECTUAL PROPERTY, TECHNOLOGY TRANSFER, AND FUNDING FOR RESEARCH: ENSURING A ROBUST PIPELINE OF BREAKTHROUGH TREATMENTS AND THERAPIES

Before I discuss new capital formation and regulatory proposals being considered by Congress, I want to highlight four laws currently in place that foster biomedical innovation.

[15] Alzheimer's Association, March 2012 Fact Sheet. http://www.alz.org/documents_custom/2012_Facts_Figures_Fact_Sheet.pdf
[16] Journal of the American Geriatrics Society, 2002, 50:1-7. via Research!America, "Facts about Alzheimer's Disease." http://www.researchamerica.org/uploads/factsheet4alzheimers.pdf

Intellectual Property/Bayh-Dole

First, Congress should be applauded for the 2011 passage and enactment of the Leahy-Smith America Invents Act, or the "patent reform bill." Small biotechnology companies rely heavily on their patents to attract investment to fund the lengthy and expensive research and development process necessary to bring breakthrough medical therapies and other products to patients and consumers. Strong intellectual property protection is critical for these companies, and they will benefit from the improvements to our nation's patent system made by this law. However, even as we speak there continue to be attacks on intellectual property in Congress and in the Courts that could be devastating to the biotechnology industry, where intellectual property is often the only asset a company has while they spend many years researching and developing breakthrough medicines.

In addition to protecting intellectual property, it is imperative that we protect Bayh-Dole, the law that has for past three decades enabled the effective transfer of technology from basic research institutions to industry so that scientific discoveries can be developed into products that will benefit the public. Prior to enactment, the vast majority of university early-stage research languished because there was no protection against competition and thus little incentive for the private sector to invest the substantial sums of money required to develop these findings into products. The 2010 Association of University Technology Managers survey clearly shows the positive impact of the Bayh-Dole Act with 4,284 licenses executed, 657 new commercial products introduced, and 651 start-up companies formed in 2010.[17] Additionally, a 2009 economic impact study showed that from 1996 to 2007 university-licensed products contributed more than $82 billion to the GDP.[18] This law is working well.

Therapeutic Discovery Project (TDP)

In March of 2010, Congress enacted the Therapeutic Discovery Project (TDP), a critical tax credit program designed to stimulate investment in biotechnology research and development.

[17] AUTM Licensing Activity Survey: FY2010. Association of University Technology Managers. http://www.autm.net/FY_2010_Licensing_Survey/7008.htm

[18] "The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007." David Roessner, Jennifer Bond, Sumiye Okubo, & Mark Planting, 3 September 2009. http://www.oregonbio.org/Portals/0/docs/Education/BIO_EDU_partnership_final_report.pdf

Under this program, small biotech companies received a much-needed infusion of capital to advance their innovative therapeutic projects while creating and sustaining high-paying, high-quality American jobs.

In total, the Therapeutic Discovery Project awarded $1 billion in grants and tax credits to nearly 3,000 companies with fewer than 250 employees each. These small companies were eligible to be reimbursed for up to 50% of their qualified investment in activities like hiring researchers and conducting clinical trials. The impact of this funding was felt across the American biotech industry, as companies in 47 states received awards. The average company received just over $200,000, an important shot in the arm during economically constrained times.

The Therapeutic Discovery Project was a significant step in the right direction by Congress to invest in growing the U.S. biotech industry and keep pace with our global competitors. Given the imbalance between the extraordinarily high demand by small biotech companies and the limited pool of funds, I hope that Congress will extend and expand this oversubscribed program and assist more American companies in pursuing life-saving scientific breakthroughs and supporting American jobs.

SBIR Reauthorization

Lastly, I would like to the thank this Committee for its commendable work over the years and applaud its success in helping reauthorize the Small Business Innovation Research (SBIR) program last year. This reauthorization reinstated eligibility for a vast majority of companies that had been shut out of the program for the past decade, due to a regulatory ruling that made small companies who have multiple venture capital investors ineligible. SBIR provides a critical source of funding for emerging biotechnology companies in the early development stages of medical research; the changes included in the reauthorization will enable a larger number of small companies to compete for funding, thus ensuring that the program will be able to fund small biotech companies' projects that have the greatest potential to bring innovative medical treatments to the patients who need them. BIO looks forward to working with Congress as these reforms are implemented by the Small Business Administration and in the participating agencies and institutes.

RE-ENGINEERING THE ECONOMIC MODEL TO INCENTIVIZE BIOMEDICAL INNOVATION

As I previously noted, U.S. biotech companies are facing financial uncertainty in a climate where other countries are increasing their investments and enacting intellectual property protections to encourage domestic biotech growth. While we still hold our place as the global leader, the competitive gap is getting smaller. For example, the U.S. currently holds the largest number of biotechnology patents overall, but we are 20th out of 23 countries in new biotech patents, with China and India ranking first and second.[19] These emerging powers are heavily investing in science, and particularly in biotechnology. Additionally, many countries in Western Europe are implementing biotech-friendly tax incentives, including lower corporate tax rates for innovative industries, as a means to grow their 21st century economies. This lag has put us at risk of losing our place at the forefront of this critically important and innovative economic driver.

Below I will briefly highlight some tax and capital formation proposals currently being discussed that would incentivize investment in small, emerging biotechnology companies and inspire further development on groundbreaking cures and treatments.

R&D Partnership Structures

Congress has historically provided tax incentives to high-risk industries as a means for encouraging investment in new endeavors. Biotechnology companies have among the largest capital burdens and longest development pathways of any industry, to determine whether their technologies will succeed. These high costs and long timelines can scare off investors who may be looking for investment strategies with earlier prospects for success. In the past, Congress has provided tax incentives that mitigate risk and enhance the returns of innovative development projects like those found in biotechnology companies. In particular, the growth of the biotech industry in the early 1980s was due in part to the ability of growing companies to pass through various tax incentives, including credits and losses, to their investors. These passive activity provisions allowed investors to realize an earlier return on their investment, thus incentivizing them to invest at an early stage. Amending the Internal Revenue Code of 1986 to allow certain tax incentives stemming from R&D to flow through from life science projects to their investors

[19] "Gone Tomorrow? A Call To Promote Medical Innovation, Create Jobs and Find Cures in America." The Battelle Technology Partnership Practice, 2010. Prepared for The Council for American Medical Innovation.

would result in immediate tax benefits to investors and thus attract more investment in small biotechnology companies.

Section 382 Net Operating Loss (NOL) Reform

The long, capital-intensive development period intrinsic to biotechnology means that companies often undergo a decade or more of research and development without any product revenue prior to commercialization. During this time period, companies generate significant losses, which can be used to offset future gains if the company becomes profitable. However, Section 382 of the Internal Revenue Code restricts the usage of net operating losses (NOLs) by companies that have undergone an "ownership change." This section was enacted to prevent NOL trafficking, but small biotech companies are caught in its scope, as their reliance on outside financing and deals frequently trigger the ownership change restrictions. There are two reforms to Section 382 that would be beneficial to small biotechnology companies. First, exempt NOLs generated by qualifying research and development by a small business from Section 382 and second, redefine "ownership change" to exclude certain qualified investments, like those in rounds of venture financing. These reforms would allow small biotech companies to retain their NOLs and allow them to include them as tax attributes on the balance sheet, thus increasing their value when preparing for additional rounds of financing like mergers or initial public offerings.

Section 1202 Capital Gains Reform

Section 1202 provides a small business investment tax incentive wherein taxpayers may exclude 50% of their gain from the sale of a qualified small business stock that has been held for more than five years. This tax exclusion could be useful to small biotech companies by incentivizing investors to invest early and hold their investments longer. However, due to the valuable intellectual property and successive rounds of financing inherent in capital-intensive, innovative industries, small biotech companies do not meet the definition of qualified small businesses. Thus, Section 1202 does not provide investors an incentive to invest in small biotech companies. Changing the definition of "qualified small business" to include companies with gross assets up to $150 million, indexing the cap to inflation, and excluding intellectual property and follow-on rounds of financing from the gross assets test would more accurately represent the capital-

intensive nature of innovative industries like biotechnology. Additionally, a graduated increase in the exclusion for qualified small business stock, rewarding investors who hold stock for longer and incentivizing them to continue to do so, would be extremely beneficial.

Section 197 Amortization Reform

Early-stage biotech companies often receive investments from strategic acquirers that are interested in an ongoing commercial relationship with the company. In such an acquisition, business acquirers often prefer to purchase the assets of a company. During an asset purchase, the acquirer may amortize certain intangibles under Section 197 provided that it continues using the intangibles in connection with the conduct of a trade or business. For intangibles that are subject to Section 197, the amortization of the tax basis is taken over a 15-year period. Accelerating this amortization period to a five-year period could encourage large company investors contemplating acquisitions of specific intangible assets of small biotech companies to invest at an earlier stage in the companies' research.

ENABLING MODERN FDA REGULATORY PROCESSES

PDUFA V and Modernizing FDA Legislative Proposals

As CEO of a small biotechnology company, I would like to take a moment to discuss how important timely reauthorization of PDUFA V is to the United States' biotechnology industry. To truly succeed, we need to have a strong, successful FDA. In 1992, Congress, industry, and the FDA worked together to create the Prescription Drug User Fee Act (PDUFA). This program ensures that FDA has the ability to hire reviewers to expedite the drug approval process by having industry pay "user fees." PDUFA has been a tremendous success. This year, the program is set for its fifth reauthorization, "PDUFA V," which will work to get the FDA back to the basics of approving lifesaving therapies and cures. PDUFA V will enhance the drug development and review process by increasing transparency and scientific dialogue, advancing regulatory science, and strengthening post-market surveillance. Most importantly, from the standpoint of innovative companies, our hope is that PDUFA V will provide patients and doctors with earlier access to breakthrough therapies. The FDA's commitment in the PDUFA V technical agreement to the principle that timely, interactive communication with biotechnology

and life science companies during drug development is a core Agency activity will be of great value, especially to small biotechnology companies such as mine.

While my testimony today will focus on Congressmen Stearns' and Towns' Faster Access to Specialized Therapies (FAST) Act, there are several proposals being considered by Congress that I also believe would serve to improve our ability to develop and deliver innovative medicines.

First, we need to have a well-funded FDA. While industry user fees play an important role in supporting FDA's medical product review program, user fees should be complementary and additive to a sound base of appropriated resources for the Agency, and I encourage ongoing Congressional support for the Agency.

Second, FDA's mission statement should be updated to reflect the Agency's critical role in advancing innovation. This would encourage FDA to apply its rigorous standards in the most innovation-friendly manner, striving to reduce the time of drug development, so that innovative treatments are made available to the patients who need them as expeditiously as possible. Additionally, we need to provide FDA with the authorities and structure that will better enable them to keep pace with the latest scientific advances and ensure innovative tools and approaches are integrated in the FDA review processes to ensure the timely and efficient review of innovative products, and to incentivize the development and utilization of modern scientific approaches to research and development.

Third, we need to encourage FDA to be more clear and consistent in its application of standards and its communications with drug developers. Currently, standards often appear to be inconsistently applied across different divisions of the Agency. In addition, clear reasons are not given when drugs are not approved, and what should be simple, rapid communications between the FDA and developers often become bogged down in processes that take months. Finally, and not least, critical written guidances for industry often take years to be published, if at all.

When application of drug approval standards and Agency decision-making are hard to predict, the burden on innovation increases. This is particularly problematic for smaller companies that have very limited resources and are dependent on only one or two programs. All of these issues

serve to prolong the drug development process and/or to inject so much uncertainty that investors are discouraged from investing in medical innovation.

Fourth, Advisory Committee and external expert conflict of interest rules should be reformed to provide FDA with greater flexibility and discretion to select the most appropriate advisors, consistent with the rules that apply to other federal agencies. As it stands, the lack of access to the best available scientific experts often deprives the Agency of the first-rate information it needs to make the best decisions on behalf of patients.

Fifth, processes should be implemented to ensure that the views of patient groups are solicited and heard within the drug approval process. The FDA is routinely called upon to make fine judgments regarding the balance between risk and benefit. This cannot be fully accomplished without consideration of how the patients themselves view a given circumstance that affects their health and lives. While the Agency properly is concerned about the risks of introducing unsafe drugs to the marketplace, another key risk in the risk-benefit equation is rarely considered: that of not making an effective therapy available to patients in a timely manner. Currently, patients may speak at public Advisory Committee hearings, but there is no requirement that their input be obtained for all drug reviews.

Finally, and not least, formal processes should be implemented to encourage the FDA to apply the Accelerated Approval pathway more widely. The Accelerated Approval pathway was implemented by FDA in 1992 in response to patient groups who, after engaging the public in a dialogue about benefits of new HIV/AIDS treatments, were successful in advocating for earlier access to these life-saving medicines. Accelerated Approval allows for earlier approval of new drugs that provide a benefit for patients with serious and life-threatening diseases based on a new product's effect on surrogate or clinical endpoints that are deemed "reasonably likely to predict clinical benefit."[20] Under Accelerated Approval, FDA can approve the marketing of a drug to seriously ill patients based on earlier evidence of effect with a commitment from the sponsor to conduct further post-market studies to confirm and define the degree of clinical benefits to patients.

[20] 21 C.F.R. § 314.500; 21 C.F.R. § 601.40

The Accelerated Approval pathway has been a great success story, in part. While its use has been largely limited to certain disease areas (mainly cancer and HIV/AIDS), the pathway has benefited patients in those disease areas tremendously because it stimulated an explosion of investment in innovation. For example, there are now over 20 medicines for HIV/AIDS on the market. In oncology, FDA has granted Accelerated Approval to 49 new indications for 37 novel oncology drug products since 1995.[21]

There are many other serious and/or rare conditions that have been effectively excluded from the Accelerated Approval pathway. Accelerated Approval pathway needs to be modernized to incorporate the remarkable advances in life sciences that have been and will continue to be made, in such areas as genomics, molecular biology, and bioinformatics. These and other advances can enable novel drug development strategies, employing tools such as biomarkers, pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs – for example, adaptive clinical trials. Clarification of when and how these tools can be utilized in an Accelerated Approval pathway will not only incentivize drug development for serious and life-threatening diseases, but will encourage the development and utilization of still more tools and methodologies.

Enactment of H.R. 4132, the Faster Access to Specialized Treatments (FAST) Act would achieve these objectives.

Conclusion

Today I have discussed laws and proposals that would go a long way in fostering biomedical innovation in the United States. The decisions that Congress makes now will play a key role in whether or not we hold on to our global leadership in this area and maximize the economic and public health solutions that the biopharmaceutical industry has to offer. Thank you for the opportunity to share my thoughts with you today.

[21] Dr. Paul Kluetz. ODAC. February 8, 2011, the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC)