**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| MERCK & CO., INC.,<br><br>PLAINTIFF,<br>V.<br><br>XAVIER BECERRA, U.S. SECRETARY OF HEALTH & HUMAN SERVICES; CHIQUITA BROOKS-LASURE, ADMINISTRATOR OF CENTERS FOR MEDICARE & MEDICAID SERVICES; AND CENTERS FOR MEDICARE AND MEDICAID SERVICES,<br><br>DEFENDANTS. | ) | CASE NO. 1:23-CV-01615 |

**UNOPPOSED MOTION BY ECONOMISTS AND SCHOLARS OF HEALTH POLICY FOR LEAVE TO FILE ATTACHED AMICUS BRIEF IN SUPPORT OF NEITHER PARTY**

Amici curiae economists and scholars of health policy respectfully move the Court for leave to file the attached brief in support of neither party in this case. Granting the motion would "not unduly delay the court's ability to rule on any pending matter." Rule LCvR (o)(2).

Amici are the following economists and health policy scholars, each of whom focuses his work on healthcare markets and pharmaceutical drug pricing.

William S. Comanor

Distinguished Research Professor, Fielding School of Public Health, UCLA

Professor of Economics, emeritus, UCSB

Formerly, Chief Economist, US Federal Trade Commission

H.E. Frech, III

Professor of Economics

Professor of Technology Management
University of California, Santa Barbara

Mark V. Pauly
Professor of Health Care Management, emeritus
Professor of Economics, emeritus
Formerly, Director of the Leonard Davis Institute of Health Economics
University of Pennsylvania

Because *amici* are economists and scholars of health policy, not lawyers, they do not directly address the parties' competing constitutional arguments about the drug-pricing provisions of the Inflation Reduction Act. They do, however, seek to provide the Court with background necessary to understand the context in which the parties' constitutional arguments arise—context concerning the economics of the Medicare market; the relationship between intellectual property rights, drug prices, and innovation in the markets for branded pharmaceutical products.

As noted, counsel for amici economists and scholars contacted counsel of record for both plaintiffs and all defendants to obtain their consent to the filing of the attached amicus brief. As of the filing of this motion, no party has objected.

October 30, 2023

Respectfully submitted,

*/s/ Donald I. Baker*
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**CERTIFICATE OF SERVICE**

I hereby certify that on October 30, 2023, I filed this forgoing motion through the Court's CM/ECF system. I understand notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

*/s/ Donald I. Baker*
Donald I. Baker

# EXHIBIT A

## PROPOSED BRIEF OF ECONOMISTS AND AUTHORITIES IN HEALTH POLICY AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

**IN THE UNITED STATES DISTRICT COURT**
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**BRIEF OF ECONOMISTS AND AUTHORITIES IN HEALTH POLICY AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY**

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## INTRODUCTION AND INTEREST OF THE AMICI CURIAE[1]

The Amici are economists who have long studied pharmaceutical pricing issues and have recently published two professional papers on such matters.[2] As this case concerns fundamental questions of federal policy toward branded pharmaceutical pricing, we offer what we believe to be a useful perspective on this subject. It rests on relevant data dealing with US pharmaceutical supply that could have direct bearing on the issues raised in this litigation. However, as none of us is a lawyer, we take no position on the constitutional arguments that are made.

William S. Comanor

Distinguished Research Professor, Fielding School of Public Health, UCLA

Professor of Economics, emeritus, UCSB

Formerly, Chief Economist, US Federal Trade Commission

H.E. Frech, III

Professor of Economics

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University of California, Santa Barbara

[1] Statement of Authorship and Financial Contributions: Pursuant to D.C. Cir. Rule 29(a)(4)(E), no person, party, or party's counsel, outside the amicus curiae or its counsel, authored any part of this brief or contributed money that was intended to fund preparing or submitting this brief.

[2] H.E. Frech, III, M.V. Pauly, W.S, Comanor, J.R. Martinez, "Costs and Benefits of Branded Drugs; Insights from Cost-Effectiveness Research." *Journal of Cost-Benefit Analysis*, 13(2), 2022, pp. 1-16; and "Pharmaceutical Pricing, and R&D as a Global Public Good", NBER Working Paper 31272, May 23 2023; Available at www.nber.org/ppers/w31272.

Mark V. Pauly

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Professor of Economics, emeritus

Formerly, Director of the Leonard Davis Institute of Health Economics

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**ARGUMENT**

The Inflation Reduction Act significantly alters industry conduct and outcomes. Interpreting its provisions thereby requires a hearty dose of pharmaceutical economics, particularly as it pertains to the pricing of branded pharmaceuticals. In this Brief, the Amici include economic findings that flow from their research. The Amici thus seek to clarify the economic record.

1. *The economic structure of US pharmaceutical supply, created by the Hatch Waxman Act of 1984, is different from other economic markets.*

Under that law, the branded industry is separate and distinct from its generic counterpart. Its legal and economic setting is very different, and the current litigation deals only with the former.

While the branded industry receives approximately 70% of all pharmaceutical revenues, it supplies only about 10% of all retail prescriptions. As a result, branded revenues per prescription are quite high and reached an average of $653 per prescription in 2019. In contrast, average generic revenues were just $23 per prescription.[3] These striking differences are indicative of the separate industries promoted by the regulatory reform embodied in the Hatch-Waxman Act.

That legislation emerged from recognition that in the case of pharmaceuticals, there are conflicting public policy objectives: a) setting low, competitive prices, but also b) promoting a

[3] IQVIA Institute for Human Data Science, Medicine Spending and Affordability in the United States, May 1920, pp. 6,33,35.

rapid pace of new product introduction leading to improved population health.[4] As recognized by the Federal Circuit Court of Appeals:

> "The Act emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[5]

In the presence of these conflicting objectives, that law set the stage for two distinct industries to emerge, each with a different policy objective. In effect, the branded industry was tasked with finding, testing, and introducing new and improved pharmaceuticals. In contrast, the generic pharmaceutical industry was designed to provide the low prices associated with highly competitive markets.

The basic point here is that no one can accurately evaluate the economic effects of the prices set for branded pharmaceuticals without considering their impact on pharmaceutical R&D and the probable improved health benefits.

2. *Branded drugs are priced according to their associated health benefits.*

While the impact on branded pharmaceutical prices of their potential therapeutic benefits has long been recognized,[6] our first recent paper explores the relevant magnitudes. We estimate average branded producer prices, those paid predominantly by insurance companies and government programs, not in terms of prescriptions or tablets or vials but rather in reference to the Quality Adjusted Life Years (QALYs) projected from using the drug.

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[4] *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323,1326 (Fed. Cir. 2001).
[5] *Abbott Labs. v. Young*, 287 U.S. App. D.C. 190, 920 F.2d 984 (1990).
[6] Z. John Lu and William S. Comanor, "Strategic Pricing of New Pharmaceuticals," *Review of Economics and Statistics*, Vol. 80, No. 1, Feb. 1998.

The underlying data were derived from the extensive medical literature reporting the cost-effectiveness of individual drugs. By analyzing these data, the Amici reported that the average price per QALY of branded pharmaceuticals fell below $40,000.[7] That sum is not the amounts paid by individuals but rather by health insurers or government programs. In other words, those amounts are paid collectively through insurance premiums or taxes for the statistical lives gained potentially from pharmaceutical use. According to IQVIA data, in 2019, only 19% of net payer outlays were paid out-of-pocket by patients.[8]

Whether that price is large or small depends on the value received in the form of improved public health from such payments. In other words, the answer turns on how much US citizens evaluate an additional QALY.

In an outstanding volume, Viscusi summarizes the large literature of such studies and reports that our citizens value a statistical life year at more than $200,000.[9] In addition, a US Government report finds the appropriate value of a QALY for use in regulatory analysis is at least $230,000 for 2016 in 2014 dollars.[10] By these standards, the average price charged currently for new branded pharmaceuticals lies much below their projected values.

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[7] H.E. Frech, III, M.V. Pauly, W.S, Comanor, J.R. Martinez, "Costs and Benefits of Branded Drugs; Insights from Cost-Effectiveness Research." *Journal of Cost-Benefit Analysis*, 13(2), 2022, pp. 1-16.

[8] IQVIA Institute for Human Data Science, Medicine Spending and Affordability in the United States, May 1920, p. 6.

[9] Kip Viscusi, *Pricing Lives: Guideposts for a Safer Society*, Princeton University press, 2018, p. 107.

[10] U.S. Department of Health and Human Services, "2016 Guidelines for Regulatory Impact Analysis," Washington, DC, p. 21.

3. *Higher drug prices fund and incentivize socially valuable pharmaceutical R&D which is not duplicated by government programs.*

As noted in a recent report from the Congressional Budget Office, the pharmaceutical industry devoted $83 billion to R&D expenditures in 2019.[11] Their purpose was to discover and develop new and more effective drugs with significant health advantages.

A recent study noted that US life expectancy had lengthened by 3.3 years between 1990 and 2015,[12] and sought to identify the causes for this large improvement. In first place, the authors reported, were Public Health measures, and while in second place were Pharmaceuticals, which they found responsible for over a third of this improvement. From this and other studies, the evidence indicates that pharmaceutical R&D is an important investment in improved health.

However, as many point out, industry efforts are not the sole source of such improvements. Federal government efforts, largely through the National Institutes of Health (NIH) certainly play a role. Thus in 2020, NIH funding reached $41 billion, or roughly half that of industry funding.[13]

It is misleading, however, to consider industry and government funding as alternatives. On this point, the CBO Report is clear: "Public-sector research … [and] private R&D … are complements, not substitutes."[14] While NIH research is appropriately devoted to basic scientific research, industry R&D is more specifically directed towards finding and testing new pharmaceuticals. This conclusion is supported in a recent National Academy of Sciences report

[11] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, 2021, p.1.
[12] Jason D. Buxbaum, et al., "Contributions of Public Health, Pharmaceuticals, and Other Medical Care U.S. Life Expectancy Changes, 1990-2015," *Health Affairs*, 39, No. 9, 2020, pp. 1546-1556.
[13] CBO Report, p. 18.
[14] Ibid., p. 19.

that acknowledged: "Researchers involved in basic research are often poorly positioned to develop their findings into a commercially viable product."[15]

An important difference between government and industry efforts flow from the industry having to support the FDA mandated clinical trials that are designed to determine the safety and efficacy of prospective agents. Indeed, the largest components of industry R&D are outlays mandated by government regulators.

Both government and industry R&D are essential parts of the drug discovery process. While the former is financed through tax revenues, the latter is supported by private investments incentivized by drug prices that exceed production costs.

In this setting, were prices set closer to production costs, branded companies would be less incentivized to invest in new products with more uncertain prospects. What matters here are the incentives driving investment decisions, which directly depend on current margins over direct costs.

4. *US branded drug prices provide global health benefits*.

Our second paper by the amici explores the global nature of the benefits derived from pharmaceutical R&D.[16] In that context, see the data provided in Table 1. While US branded prices are much higher than the three comparison countries, it is also the case that US generic prices are much lower. Indeed, US generic prices are lower than average among OECD countries even while US branded prices are the highest.

[15] National Academy of Sciences, *Making Medicines Affordable*, 2017, pp. 39-40.
[16] H.E. Frech, III, M.V. Pauly, W.S, Comanor, J.R. Martinez, "Pharmaceutical Pricing, and R&D as a Global Public Good", NBER Working Paper 31272, May 23, 2023; Available at www.nber.org/ppers/w31272.

The essential reason for this disparity is that pharmaceutical R&D, largely funded by high US prices and designed to develop new, more effective drugs, is a "global public good" whose benefits are realized everywhere. As a result, the normal link between outlays and benefits is broken. Whatever any single country pays to supports pharmaceutical R&D, it generates the medical benefits that are available everywhere.

The US pharmaceutical market is the world's largest with nearly half of all branded pharmaceutical sales among OECD countries.[17] As a result, US residents gain the health benefits resulting largely from US contributions. For smaller countries, however, their calculus is very different since the flow of new drugs emanating from high US support for pharmaceutical R&D effectively determines the availability of new and improved pharmaceuticals in all countries. In that case, for many countries, there is little reason to add much to the US contribution.

US drug prices are high because the relevant buyers, mostly insurance companies and government programs, adopt the Hatch-Waxman mandate to promote advanced pharmaceutical therapies; and critically are willing to pay for them. Countries elsewhere do not have to face this choice since US buyers are largely but not exclusively footing the bill.

While drug companies seek maximum returns everywhere, what they can actually attain depends on finding buyers with sufficiently high "willingness to pay" amounts. The economic issues here are discussed more fully in our recent paper.[18]

[17] U.S. Council of Economic Advisers, "Reforming Biopharmaceutical Pricing at Home and Abroad," February 2018, p. 11.
[18] H.E. Frech, M.V. Pauly, W.S, Comanor, J.R. Martinez, 2023, op. cit..

5. *How drug prices are determined thorough negotiations and bargaining*

The current litigation concerns negotiations between drug companies as sellers and Medicare, which dispenses about 30% of all retail prescriptions.[19] For the prospective Medicare negotiations, there are insights to be gained from those currently entered into by drug companies and private buyers, essentially the large insurance companies represented generally by Pharmacy Benefit Managers (PBMs). These negotiations are typically confidential so little is reported on the process although a recent study offered evidence on their apparent outcomes.

See Figure 1, that describes the increasing discount off list prices negotiated by PBMs and insurance companies. Between 2007 and 2018, list prices for a large sample of drugs increased by 9.1% annually while net prices increased at half that rate, or by 4.5%.[20] Apparently, negotiations led to much lower prices than those originally announced by drug companies.

To understand this process, we turn to the economic theory of bargaining; and here distill some essential points:

a) The theory applies when both sides gain when an agreement is reached but lose in the absence of an agreement.

b) Both sides therefore have an incentive to compromise.

c) To project likely outcomes, the theory emphasizes the critical importance of each party's hypothetical outcome in the absence of an agreement. This factor is relevant even when an agreement is actually reached.

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[19] IQVIA Institute for Human Data Science, Medicine Spending and Affordability in the United States, May 1920.

[20] Hernandez, I., San-Juan-Rodriguez, A., Good, C.B., & Gellad, W. (2020). Exhibit 1, Table 1 - "US Pharmaceutical Price Indices as Percentage of Other-Country Price Indices; Exhibit 2, "Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US," 2007-2018. *JAMA*, March 3, 2020, Vol. 323, pp. 857-862.

d) The party with the poorest hypothetical outcome in the absence of an agreement has the most to gain from the presence of an agreement. And the party with the most favorable outcome in the absence of an agreement has the least to gain from the presence of an agreement.

e) More advantageous outcomes accrue to the side who can best withstand the absence of an agreement – even when agreements are reached that benefit both sides. To avoid a very bad alternative without an agreement, that party will accept an agreement even when it offers a relatively poorer outcome.

f) Bargaining ability also matters; but is commonly considered equal in the absence of specified factors.

To apply these theoretical principles to drug company–Medicare negotiations, both sides would gain when an agreement is reached: the drug company gains the resulting revenues, while Medicare fulfills its public purpose of supporting needed pharmaceuticals to seniors. In that case, one might expect to find similar outcomes to those found in the private sector or in drug company negotiations with other public agencies such as the VA.

Applied to the case at hand, however, the proposed negotiation process is differentiated by the high excise tax that can be assessed in the absence of an agreement negotiate on the selected drugs. A drug company engaged with Medicare could not afford the absence of a price agreement if (i) a punitive tax would then be levied on all the company's Medicare sales, or (ii) the company had to withdraw from all Medicare sales to avoid the tax when it declined to negotiate over any selected drugs. In either case, the serious economic impact on the drug company would determine its minimum acceptable price

While the economics is clear, the legal situation seems less so. The parties have very different approaches to what options a drug company has if wants to opt out of negotiations over a selected drug. The Plaintiff sees it as an *all or nothing process vis-à-vis participation in the entire Medicare/Medicaid program.*[21]

In contrast, the government sees it as *an a la carte process on which the company can make choices limited to the selected drugs,*[22] and it can still withdraw from the negotiations after it sees Medicare's proposed price. As economists, the Amici take no position on this legal issue that divides the parties. However, they emphasize that this legal issue is very important. In applying economic analysis, bargaining outcomes depend critically on the circumstances in which either party can exercise a clear right withdraw from the bargaining process if dissatisfied with it. This conclusion is fully applicable to the negotiated bargaining process mandated by the Inflation Reduction Act.

October 30, 2023

Respectfully submitted,

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[21] "While the excise tax is suspended if the manufacturer has no relationship with Medicare or Medicaid,…[that involves] leveraging all federal insurance benefits (amounting to over half of the prescription drug market) to coerce companies." *Merck v. Xavier Becerra et al*., Complaint, June 6, 2023, p. 3.

[22] "if a manufacturer is unwilling to sell its selected drugs to Medicare at the price the government is willing to pay, it is free to withdraw from the Medicare program. Alternatively, if the manufacturer wishes to remain in Medicare but for some reason unwilling to negotiate over the price of its selected drugs, the IRA imposes an excise tax on sales of those selected drugs to Medicare." Defendants' Motion in Opposition to the Plaintiffs' Motion for Summary Judgment pp. 21-22.

**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION**

Pursuant to FRAP 29(a)(4) and LCvR 5.1, I hereby certify that this brief complies with the type-volume limitation of because it contains 2,162 words. I further certify that this brief complies with the typeface requirements of LCvR 5.1 because this brief has been prepared in a proportionally spaced typeface using Word in 12-point Times New Roman.

*/s/ Donald I. Baker*

tDonald I. Baker

# Exhibit 1

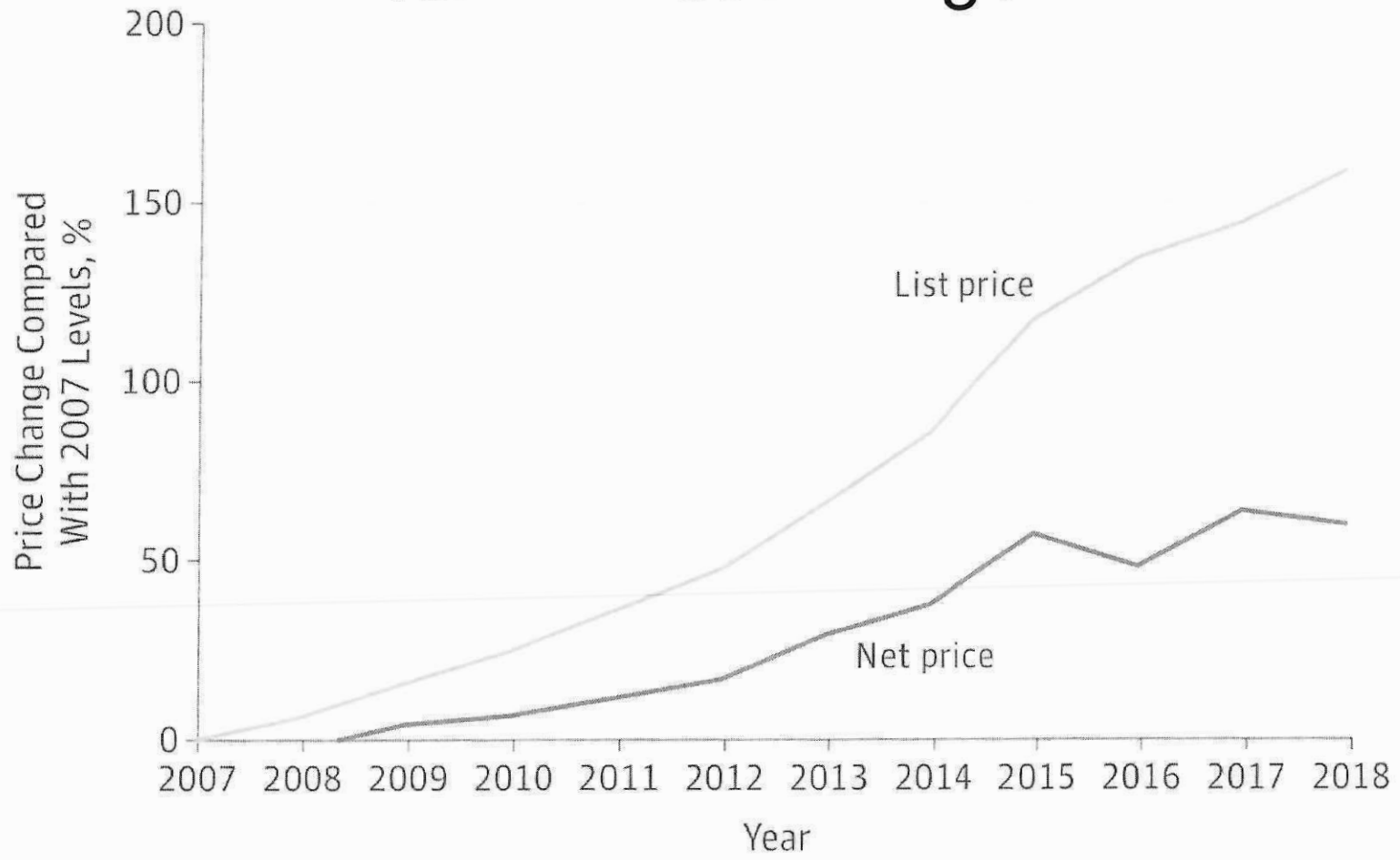
# Table 1
# US Pharmaceutical Price Indices
# as Percentage of Other-Country Price Indices, 2018

| | Japan | Germany | U.K. |
|---|---|---|---|
| US Branded Originator Prices | | | |
| Invoice Prices | 307% | 280% | 349% |
| Net Prices After Correction | 206% | 187% | 234% |
| Unbranded Generic Prices | 43% | 62% | 68% |

*Source:* Rand Research Report, "International Prescription Drug Price Comparisons," (2021), pp. 27, 35, 28.

# Exhibit 2

# Figure 1
# Changes in List and Net Prices for Branded Drugs




*Source:* Hernandez, I., San-Juan-Rodriguez, A., Good, C.B., & Gellad, W. (2020). "Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US," 2007-2018. *JAMA*, March 3, 2020, Vol. 323, p. 857.

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**[PROPOSED] ORDER GRANTING LEAVE TO ECONOMISTS AND HEALTH POLICY SCHOLARS WILLIAM S. COMANOR, H.E. FRECH, III AND MARK V. PAULY TO FILE BRIEF AS *AMICI CURIAE***

Having considered the unopposed motion of economists and health policy scholars William S. Comanor, H.E. Frech, III and Mark V. Pauly for leave to file a brief as *amici curiae* in support of neither party, the Court hereby **GRANTS** the motion and directs the Clerk of the Court to file the brief submitted simultaneously with the Motion.

_____ _____

DATED

HONORABLE COLLEEN KOLLAR-KOTELLY
SENIOR UNITED STATES DISTRICT JUDGE