24-2092-cv

United States Court of Appeals

for the

Second Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

– v. –

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, In His Official Capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, CHIQUITA BROOKS-LASURE, In Her Official Capacity as Administrator of Centers for Medicare and Medicaid Services,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

AMICUS CURIAE BRIEF OF ATLANTIC LEGAL FOUNDATION IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

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INTEREST OF THE *AMICUS CURIAE* [1]

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, public interest law firm. Its mission is to advance the rule of law by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state appellate courts. *See* atlanticlegal.org.

[1] Appellant and Appellees have consented to the filing of this brief. In accordance with Federal Rule of Appellate Procedure 29(a)(4)(E), undersigned counsel hereby states that no party's counsel authored this brief in whole or part, and no party or party's counsel, and no person other than the *amicus curiae*, its supporters, or its counsel, contributed money that was intended to fund preparing or submitting the brief.

This appeal presents important constitutional questions that squarely align with ALF's free-enterprise and limited-government advocacy missions. These questions include whether the Inflation Reduction Act's Drug Price Negotiation Program—a price-control Program that sets the government-imposed "maximum fair price" that pharmaceutical manufacturers can charge under Medicare/Medicaid for their most innovative, widely prescribed, brand-name products—violates the Fifth Amendment's Due Process and Takings Clauses and/or the First Amendment's Free Speech Clause. Rather than repeating Plaintiff-Appellant's arguments concerning why the Program directly violates these fundamental constitutional rights, this amicus brief addresses the related issue of whether, and why, the Program also violates the unconstitutional conditions doctrine.

Another of ALF's primary missions—advocating for sound science—also is at stake in this case. The discovery and development of new life-saving drugs is an arduous, extraordinarily expensive and financially risky, multi-phase scientific process that requires a continuous infusion of funds derived from sales of the tiny fraction of potential products that survive extensive preclinical laboratory research,

human clinical testing, and Food and Drug Administration (FDA) regulatory review and approval. Government-imposed price controls undermine this crucial process, and thus, are contrary to the public interest.

INTRODUCTION

Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc. filed this action in Connecticut federal district court challenging the misleadingly named Drug Price Negotiation Program ("the Program"), 42 U.S.C. § 1320f *et seq.*, enacted as part of the Inflation Reduction Act of 2022. Boehringer is the research-oriented company that invested billions of dollars and years of time to develop Jardiance®—a prescription medication that FDA has approved for a variety of uses, including treatment of type 2 diabetes and lowering that condition's cardiovascular risks. *See* Boehringer Br. at 13. Defendant-Appellee Centers for Medicare & Medicaid Services ("CMS"), which administers the Program, has designated Jardiance® as a "negotiation eligible drug" that can be sold within the enormous Medicare/Medicaid system *only* at a sharply discounted, government-dictated, "maximum fair price." *See* Ruling On

Motions For Summary Judgment (SPA 3);[2] 42 U.S.C. §§ 1320f-1 & 1320f-2; Boehringer Br. at 13-14.

Boehringer argues, *inter alia*, that the Program violates its Fifth Amendment right to procedural due process, effects a physical taking of its Jardiance® products in violation of the Fifth Amendment, and compels it to engage in speech that conveys the government's viewpoint and messaging about the Program's alleged nature and virtues. *See* Boehringer Br. at 2-3; SPA 11.

The district court's rejection of these constitutional claims is based on the legal fiction that "[Boehringer]'s participation in the Program is voluntary." SPA 31. According to the court, (i) "because [Boehringer] can opt out of Medicare and Medicaid, it has not been deprived of property for the purposes of its Due Process Clause and Takings Clause claims"; and (ii) because "[Boehringer] was free to withdraw from Medicare and Medicaid . . . the Manufacturer Agreement did not 'compel' [Boehringer] to do anything" that violates its First Amendment rights. SPA 14, 31; *see also* SPA 21 ("Voluntariness of the Program").

[2] The district court's Ruling On Motions For Summary Judgment is reproduced in Appellant's Special Appendix ("SPA") at 1-47.

Boehringer contends here, as it did in district court, that its participation in the Program, as a practical matter, not only is *involuntary*, but also violates the unconstitutional conditions doctrine. *See* Boehringer Br. at 57. This well-established doctrine applies insofar as pharmaceutical manufacturers—*regardless* of whether the Program is "voluntary"—are required, as a condition for participation, to relinquish their constitutional rights to due process, just compensation, and/or freedom of speech. Because the Constitution expressly and unequivocally prohibits the government from abridging these fundamental rights, they cannot be circumvented by forcing pharmaceutical manufacturers to surrender them as a condition for participating in the Program.

This *amicus curiae* brief endeavors to help inform the Court's decision-making by providing additional background on the unconstitutional conditions doctrine as it relates to this case. Our brief also discusses why the Program's industry-crippling price controls seriously undermine pharmaceutical companies' ability to engage in the high-financial-risk process of new drug research & development, and for that reason, ultimately *harms* the public interest.

ARGUMENT

The District Court's Judgment Should Be Reversed

A. The unconstitutional conditions doctrine invalidates the Drug Price Negotiation Program regardless of whether a pharmaceutical manufacturer's participation is "voluntary"

Boehringer persuasively argues that its constitutional rights are violated by the Drug Price Negotiation Program's built-in mandates—*e.g.*, the Program's requirement that a pharmaceutical manufacturer either participate in "negotiations" to reach "agreement" on a "maximum fair price" for its government-selected brand-name product or incur enormous financial penalties. *See* Boehringer Br. at 36-38. Even if the Program's mandates are viewed merely as conditions for voluntary participation in the Program, they are *unconstitutional* conditions, and thus render the Program invalid.

1. The unconstitutional conditions doctrine reflects an "overarching principle . . . that vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). "[R]egardless of whether the government ultimately succeeds in pressuring someone into forfeiting a constitutional right, the

unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Id.* at 606; *see also Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1377 n.4 (2018) ("The doctrine prevents the Government from using conditions 'to produce a result which it could not command directly.'") (quoting *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)).

Even though "[v]irtually all of [the Supreme Court's] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind . . . [the Court has] repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz*, 570 U.S. at 608; *see also O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) ("It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right.") (internal quotation marks omitted); Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1415 (1989) ("The doctrine of unconstitutional conditions holds that the government may not grant a benefit on the condition that

the beneficiary surrender a constitutional right, even if the government may withhold the benefit altogether.").

In short, the doctrine "limits the ability of governments to force individuals to choose between retaining a right and enjoying a government benefit." Kay L. Levine et al., *Protecting State Constitutional Rights from Unconstitutional Conditions*, 56 U.C. Davis L. Rev. 247, 249-50 (2022). It thus "reflects the triumph of the view that government may not do indirectly what it may not do directly over the view that the greater power to deny a benefit includes the lesser power to impose a condition on its receipt." Sullivan, *supra* at 1415.

From an historical perspective, the unconstitutional conditions doctrine goes at least as far back as *Frost & Frost Trucking Co. v. Railroad Commission of California*, 271 U.S. 583, 598 (1926) ("a state is without power to impose an unconstitutional requirement as a condition for granting a privilege"); *see Koslow v. Pennsylvania*, 302 F.3d 161, 173, 174 (3d Cir. 2002) (quoting *Frost & Frost*); *see generally* Louis W. Fisher, *Contracting Around the Constitution: An Anticommodificationist Perspective On Unconstitutional Conditions*, 21

U. Pa. J. Const. L. 1167, 1176-79 (2019) (presenting "A Brief Doctrinal History" of unconstitutional conditions jurisprudence).

"[T]he modern administrative state [has] contributed to the proliferation of unconstitutional conditions problems." *Id.* This escalation of governmental power is reflected by the Supreme Court's numerous decisions applying the unconstitutional conditions doctrine in a variety of contexts. *See, e.g. Koontz*, 570 U.S. at 608 (collecting cases). Unconstitutional conditions cases include takings in violation of the Fifth Amendment. *See, e.g.*, *Sheetz v. City and Cnty. of El Dorado, Cal.*, 144 S. Ct. 893, 900 (2024) ("Our decisions in *Nollan* [*v. Cal. Coastal Comm'n*, 483 U.S. 825 (1987)] and *Dolan* [*v. City of Tigard*, 512 U.S. 374 (1994)] address [the] potential abuse of the permitting process. There, we set out a two-part test modeled on the unconstitutional conditions doctrine."); *Koontz*, 570 U.S. at 604 ("*Nollan* and *Dolan* involve a special application of this doctrine") (internal quotation marks omitted).

The unconstitutional conditions doctrine also applies to government-imposed conditions that infringe upon freedom of speech. *See, e.g.*, *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) ("[W]e have held that the Government may not deny a

benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit.") (internal quotation marks omitted); *Elrod v. Burns*, 427 U.S. 347, 358 n.11 (1976) (noting the Court's "[p]rotection of First Amendment interests" by "invalidation of conditions"); *Perry v. Sindermann*, 408 U.S. at 597 (the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech"). "In *Perry*, the Court broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit . . . ." *Elrod*, 427 U.S. at 359.

2. The district court's rejection of Boehringer's constitutional claims is predicated on the supposed voluntariness of their participation in the Medicare/Medicaid system generally and the Drug Price Negotiation Program in particular.

The court agreed with the government that "that the Program does not deprive [Boehringer] of its property under the Due Process Clause or Takings Clause, because participation in the Program is voluntary." SPA 14. It disagreed with Boehringer that "withdrawing from Medicare and Medicaid is not a realistic option." *Id.* More specifically, the court

rejected Boehringer's argument that "the option to withdraw from Medicare and Medicaid does not render the Program voluntary, because forcing [it] to abandon [Medicare and Medicaid], which occupy nearly half the U.S. health care market and account for over half [Boehringer]'s sales, is economic dragooning that leaves [it] with no choice but to acquiesce to the Program." SPA 21 (internal quotation marks omitted). According to the court, "[Boehringer]'s participation in Medicare and Medicaid is voluntary, even if Boehringer has a considerable economic incentive to participate. . . . private corporations often will have an incentive to participate in federal programs." SPA 29-30.

The district court also rejected the contention "that the Program violates [Boehringer]'s First Amendment rights by compelling [Boehringer] to echo the Government's preferred narrative regarding the Program" by requiring Boehringer to sign a Manufacturer Agreement that "uses terms like 'negotiation' and 'maximum fair price.'" SPA 30 (some internal quotation marks omitted). According to the court, "[Boehringer]'s participation in the Program is voluntary, and [Boehringer] was free to withdraw from Medicare and Medicaid before

the deadline for signing the Manufacturer Agreement. So the Agreement did not 'compel' [Boehringer] to do anything." SPA 31.[3]

Boehringer's brief explains why its participation in either Medicare/Medicaid or the Program cannot reasonably be viewed as voluntary. *See* Boehringer Br. at 47-57. Indeed, CMS reports that as of June 2024, there were 67.5 million individuals enrolled in Medicare[4] and 80 million individuals in Medicaid.[5] Boehringer's supposed choice on whether to "opt out of Medicate and Medicaid," SPA 14, therefore, would be financial suicide that no publicly held company would commit. Nor should the government want to induce Boehringer and similarly situated pharmaceutical companies to deprive more than 140 million Medicare/Medicaid participants (i.e., almost half the nation) of state-of-the-art, life-saving drugs.

3. As discussed above, based on Boehringer's supposed voluntary participation in the Program, the district court concluded that the

[3] The district court also asserted that "any effects [the Program] may have on speech are 'plainly incidental.'" SPA 31.

[4] *See* Data.CMS.gov, https://tinyurl.com/ytu3deyd.

[5] *See* Medicaid.gov, https://tinyurl.com/466tdur6.

Program does not deprive Boehringer of its Fifth or First Amendment rights. And based on this erroneous conclusion, the court found that the unconstitutional conditions doctrine does not apply.

For example, the court indicated that

> the unconstitutional conditions doctrine is only implicated where the plaintiff is asked to sacrifice a constitutional right. So [Boehringer] must first establish, at minimum, that it had a First Amendment right to refuse to sign the Manufacturer Agreement, i.e., that "the government could not have constitutionally ordered [Boehringer] . . . to do what it attempted to pressure [Boehringer] into doing," *Koontz*, 570 U.S. at 612. [Boehringer] cannot make that showing.

SPA 34-35.

As to Boehringer's Fifth Amendment claims, the district court not only held that there is no physical taking of Boehringer's property, SPA 14, but also suggested that Boehringer's "voluntary" participation in the Program defeats its unconstitutional conditions argument. *See* SPA 36 ("[T]he Supreme Court has suggested that the unconstitutional conditions doctrine does not ordinarily bar the government from requiring corporations to sacrifice certain property rights to receive a voluntary government benefit.") Similarly, the court's opinion, although less than a model of clarity, appears to indicate that the voluntariness of

the Program invalidates Boehringer's unconstitutional conditions due process claims. *See* SPA 37 ("Any private firm that wants to sell to the government (or through a government funded program) must—if it wishes to continue receiving the benefit of participating in the government spending financing the purchase—surrender its product, sometimes at a price or under terms it does not like.").

4. Contrary to the district court's analysis, Boehringer's supposed voluntary, *i.e.*, consensual, participation in the Program is *irrelevant* to operation of the unconstitutional conditions doctrine where, as here, companies must relinquish their constitutional rights as a condition for receiving a governmental benefit (e.g., participation in the Medicare/Medicaid system). *See* Philip A. Hamburger, *Unconstitutional Conditions: The Irrelevance of Consent*, 98 Va. L. Rev. 479 (2012). Indeed, the district court's opinion concedes this point. *See* SPA 34 ("The fact that [Boehringer]'s participation in the Program is voluntary is not dispositive[.]"). But the court's opinion then relies on the alleged voluntary nature of the Program, *inter alia*, to conclude that the unconstitutional conditions doctrine does not apply.

5. Professor Hamburger's often-cited article on *The Irrelevance of Consent* explains that "consent is irrelevant for conditions that go beyond the government's power." Hamburger, *supra* at 480. He asks:

> Can consent justify the government in exceeding its power?
>
> The key is to distinguish between the role of consent within and beyond the government's constitutional authority. . . . Undoubtedly the government can use consent within its authority, as defined by its various powers; but where these powers are limited, either in themselves or through the [Constitution's] rights and structures, the question is whether the government can rely on consent to justify going beyond these limits and thus beyond its authority. . . .
>
> The answer can be found in the simple recognition that the Constitution is a law. Being a law and, indeed, a law made by the people, *its limits are not alterable by private or state consent*, but only by the consent of the people. . . . Accordingly, the *government cannot escape its constitutional bounds by getting, let alone purchasing, the consent of any lesser body*, whether individuals, private institutions, or states. For such purposes, *their consent is irrelevant*.

Id. at 483 (emphasis added).

In other words, the unconstitutional conditions doctrine establishes that the government cannot alter, much less ignore, the prohibitions imposed by the Bill of Rights on the theory that an individual or

corporation has consented to forgo them in return for receiving a governmental benefit. *See* Fisher, *supra* at 1181 ("arguing along with Hamburger and others that the government should be presumptively prohibited from conditioning receipt of a benefit on waiver of an individual's constitutional rights").

"[T]here is a risk in allowing the government to accomplish indirectly that which it cannot do directly. If a constitutional provision prohibits the government from violating a right, why can the government condition a valuable benefit on a person forsaking that right?" Levine, *supra* at 258; *see also* Ryan C. Williams, *Unconstitutional Conditions and the Constitutional Text*, 172 U. Pa. L. Rev. 747, 800 (2024) ("If the government conditions access to a particular benefit on waiver of a nonwaivable right, then the condition cannot be met without violating the Constitution.").

Legal scholars debate the exact contours of the unconstitutional conditions doctrine. But with the growth of the administrative state,

> the threat from unconstitutional conditions [has] become of central importance, for they have become a *means of evading much of the Constitution, including the Bill of Rights*. Only by recognizing this can one begin to understand the peril of casually assuming

> that the government can purchase its way out of constitutional rights and other limits.

Hamburger, *supra* at 491 (emphasis added). The unconstitutional conditions doctrine is "charged with safeguarding liberty in the face of government's ubiquitous programming and extraordinary resources," and "is necessary to ensure that governments cannot circumvent constitutional imperatives simply by purporting to ask rather than tell." Randy J. Kozel, *Leverage*, 62 B.C. L. Rev. 109, 124 (2021).

6. In sum, the district court's conclusion that Boehringer's constitutional claims lack merit because their participation in the Program supposedly is voluntary clashes with the unconstitutional conditions doctrine. This is a compelling reason for reversing the district court.

B. If allowed to proceed, the Drug Price Negotiation Program will harm the public interest

The Biden/Harris administration has brazenly used the Drug Price Negotiation Program as a political tool for trying to win votes by demonizing "Big Pharma"—profitable companies, like [Boehringer], that continuously invest billions of dollars in discovering, testing, and gaining regulatory approval for, new life-saving drugs and vaccines.

For example, on February 1, 2024 the White House issued an "Interested Parties Memo" titled "President Biden Takes On Big Pharma and Is Lowering Prescription Drug Prices."[6] The memo hyperbolically asserts that "President Biden's drug price negotiation program finally takes on Big Pharma's exorbitant price gouging of seniors, allowing Medicare to put money back in the pockets of American families." Although the White House memo boasts that "[t]his is the first time ever that Medicare is not accepting the drug prices the pharmaceutical companies set," the government, in reality, is using the deceptively named "negotiation" program to *dictate* the significantly discounted prices that Big Pharma companies can charge under Medicare/Medicaid.

Along the same lines, on September 30, 2024, the President boasted that "[w]hile Big Pharma made record profits, Americans footed the bill for the industry's price hikes. Not anymore." Statement from President Joe Biden on Lower Prescription Drug Prices.[7]

[6] https://tinyurl.com/yn6hwbza.

[7] https://tinyurl.com/bddz29vh.

At the political sound bite level, slashing prices for the newest, most innovative, and/or widely used brand-name prescription drugs seems consistent with the public interest. But in reality, this latest form of politically motivated, government-imposed price control is short-sighted: The Program is *detrimental* to the public interest because it diminishes the financial resources that research-oriented companies like Boehringer need to reinvest in proprietary new drug research and development (R&D).

The PhRMA (Pharmaceutical Research and Manufacturers of America) website discusses the societal importance of its members' financial investments in R&D:

> Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures. While these investments continue to build upon previous medical advances, they are just beginning to yield results on the latest breakthroughs, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.
>
> America's biopharmaceutical sector is the most R&D-intensive industry in the U.S. economy. In fact, the biopharmaceutical industry invests on average six times more in R&D as a percentage of sales than all other manufacturing industries.

PhRMA, Research & Development Policy Framework.[8]

Developing and commercializing a new prescription drug—including the formidable and time-consuming challenge of obtaining FDA approval—is an extraordinarily costly and financially risky process. Myopically focusing on prices alone fails to take into account the bigger picture—the often insurmountable financial, scientific, regulatory, and/or commercial hurdles that a new drug, even one that shows promise during early testing—must overcome before it can be made available to the public.

FDA's website provides an overview of the five, universally accepted stages of new drug development in the United States:

- Discovery and Development
- Preclinical Research
- Clinical Research
- FDA Review
- FDA Post-Market Safety Monitoring

FDA, The Drug Development Process (Jan. 4, 2018).[9]

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[8] https://tinyurl.com/2p8ns6dp (last visited Oct. 14, 2024).

[9] https://tinyurl.com/mrya4fye.

Since human health and safety are at stake, each of these successive and arduous stages of new drug development involves rigorous scientific research or testing and/or intensive evaluation of scientific data. "[D]rug discovery and development is unlike any other type of development or innovation process . . . [it] carries far greater uncertainty, and the outcome is rarely assured." PharmaCentral, Drug Discovery and Development: A Step-By-Step Guide (Oct. 22, 2021).[10]

During Stage 1 (Discovery and Development), "thousands of compounds may be candidates for potential development," but "[a]fter early testing . . . only a small number of compounds look promising and call for further study." FDA, *supra*. During Stage 2 (Preclinical Research), a candidate drug's toxicity is determined, and on that basis, "researchers . . . decide whether the drug should be tested in people." *Id.* Following human trials conducted during Stage 3 (Clinical Research), only 33% of new drug candidates move on to Stage 4 (FDA Review), *id.* "Only 12% of new molecular entities that enter clinical trials eventually receive [FDA] approval." PhRMA, *supra*; *see also* Biotechnology

[10] https://tinyurl.com/y8hy5mzj.

Innovation Organization (BIO), Clinical Development Success Rates and Contributing Factors 2011-2020 (Feb. 2021).[11]

"On average, it takes 10-15 years and costs $2.6 billion to develop one new medicine, including the cost of the many failures." PhRMA, *supra*. Given the enormous investment of scientific and financial resources involved in developing a "winner," pharmaceutical companies need to earn an acceptable return to continue engaging in new drug R&D. For this reason, the Drug Price Negotiation Program not only is unconstitutional, but also harmful to the true public interest.

CONCLUSION

This Court should reverse the district court's judgment and hold that the Drug Price Negotiation Program is unconstitutional.

Respectfully submitted,

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[11] https://tinyurl.com/2as33v8y.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5), because the brief contains **3,847** words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionately spaced typeface using Microsoft 365 Word.

/s/ *Lawrence S. Ebner*

November 12, 2024

CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2024, I caused the foregoing Brief of Atlantic Legal Foundation As *Amicus Curiae* In Support of Appellant and Reversal to be electronically filed with the Clerk of Court for the Second Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ *Lawrence S. Ebner*