UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of SCHERING-PLOUGH CORPORATION, a corporation, UPSHER-SMITH LABORATORIES, INC., a corporation, and AMERICAN HOME PRODUCTS CORPORATION, a corporation.	Docket No. 9297 **PUBLIC VERSION**

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' JOINT MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. NELSON L. LEVY

Respondents seek to preclude the testimony of Dr. Nelson L. Levy, an expert in the area of pharmaceutical licensing arrangements. Dr. Levy is being offered to testify that [redacted] His opinion is based on his nearly four decades of experience in medicine, academia, and the pharmaceutical industry, and his detailed review of the record.

Respondents' joint motion is entirely without merit and should be denied because:

- Dr. Levy is qualified to render an opinion that [redacted]

- Dr. Levy's opinion is based on his expertise and detailed review of the record, not on a subjective evaluation of the credibility of fact witnesses.

I. Standard for Admissible Evidence

This proceeding is governed by the FTC's Rules of Practice. As the Supreme Court decided decades ago in *FTC v. Cement Institute*: "[A]dministrative agencies like the Federal Trade Commission have never been restricted by the rigid rules of evidence."[1] "Indeed," as the Commission has observed, "one of the purposes in establishing [tribunals such as the FTC] was to devise a way whereby the exclusionary rules of evidence would be eliminated as a bar to common sense resolution of certain classes of controverted cases."[2] Under the FTC's Rules of Practice, "[r]elevant, material, and reliable evidence shall be admitted."[3] Reliability is the key to admissibility. These principles apply equally to expert testimony as to other forms of evidence.[4] Respondents have the burden of demonstrating that Dr. Levy's testimony is unreliable.

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[1] 333 U.S. 683, 705-706 (1948). *See also* Kenneth C. Davis and Richard J. Pierce, Jr., II *Administrative Law Treatise* (3d ed. 1994) § 10.3 at 125-126 (observing that "it makes little sense to take the risk of erroneous exclusion of reliable evidence through application of highly technical exclusionary rules in the context of agency adjudications"). Indeed, even in the context of a bench trial, court often apply more liberally the Federal Rules of Evidence, which were designed primarily to govern decision-making by juries. *Volk v. United States*, 57 F. Supp. 2d 888, 896 n.5 (N.D. Cal. 1999) (observing that the "*Daubert* gatekeeping" function is "less pressing" in connection with a bench trial because the judge and the fact finder are the same); *Ekotek Site PRP Committee v. Self*, 1 F. Supp. 2d 1282, 1296 (D. Utah 1998) (admitting expert testimony despite "reservations" about methodology); *Fierro v. Gomez*, 865 F. Supp. 1387, 1396 n.7 (N.D. Cal. 1994) (stating that the better approach under *Daubert* in a bench trial is to permit expert testimony subject to cross-examination), *aff'd on other grounds*, 77 F.3d 301 (9th Cir. 1996), *vacated and remanded on other grounds*, 519 U.S. 918 (1996).

[2] *Philadelphia Carpet Co.*, 64 F.T.C. 762, 773 (1964) ("it is long settled that hearsay evidence is not to be out of hand rejected or excluded by administrative tribunals").

[3] 16 C.F.R. § 3.43(b) (emphasis added).

[4] Even under the Federal Rules, the "rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702, Advisory Committee Notes.

II. Dr. Levy Is Qualified To Render A Reliable Opinion As To Whether Schering's $60 Million Payment Could Reasonably Be Considered a Licensing Fee for Niacor-SR

Dr. Levy is being offered to testify that [redacted] Based on his detailed review of the record and his extensive practical experience in the pharmaceutical industry, he reaches this opinion from the following three conclusions:

- [redacted]
- [redacted]
- [redacted]

A. Dr. Levy's Relevant Experience

Dr. Levy has had a distinguished career in medicine, academia, and the pharmaceutical industry that makes him well qualified to offer his reliable opinion that the $60 million up-front guaranteed payment by Schering to Upsher was not for the Niacor-SR license. Dr. Levy has received degrees from prestigious universities, including his M.D. from Columbia and a Ph.D. in immunology from Duke. He has conducted research at NIH in the areas of virology and immunology and was an associate tenured professor at Duke.[5]

[5] *Curriculum Vitae* of Dr. Levy (Attachment A).

Dr. Levy's extensive experience in the pharmaceutical industry began two decades ago and continues to this day. During this time, he has worked for two multi-national pharmaceutical companies. As vice-president of pharmaceutical research for Abbott Laboratories, Dr. Levy was involved in the design and conduct of clinical studies necessary for FDA approval, and started the research program that led to the FDA's approval of three products. He also worked closely with Abbott's licensing/business development group and domestic and international marketing organization, participating regularly in senior-level meetings to decide whether to in-license pharmaceutical products, including cardiovascular drugs, for sales in both the United States and overseas. As Chief Executive Officer of the U.S. subsidiary of Fujisawa Pharmaceutical Company, Dr. Levy was responsible for all areas of the company's operation including marketing, sales, business development (*e.g.*, in-licensing of pharmaceutical products), finance, regulatory approval, and research and development. While at Fujisawa, Dr. Levy in-licensed four major pharmaceutical products.

In addition to these senior positions at two major pharmaceutical companies, Dr. Levy has developed broad and varied experience in the pharmaceutical and biotech industries through CoreTechs, the company he formed more than 15 years ago. As Chief Executive Officer and Chairman of CoreTechs, Dr. Levy has provided consulting services to numerous pharmaceutical and healthcare companies on various aspects of the companies' operations, including research and development, evaluation of products for in-licensing, and marketing. At CoreTechs, he has evaluated dozens of products and technologies and has advised major pharmaceutical companies on decisions concerning the marketing and sale of pharmaceuticals overseas. As just one example of his consulting services, Dr. Levy assisted a company in its international research and

development efforts by spending several weeks each year over a two year period on site at its Italian subsidiary. Through his work at CoreTechs, Dr. Levy also has become heavily involved in assisting developing companies to evaluate their technology and determine the optimal means to develop and market their technology and products.

Over the last two decades, Dr. Levy also has served on the boards of directors and scientific advisory boards for numerous major pharmaceutical and biotech companies. In these advisory capacities, Dr. Levy's input and advice (and approval in some circumstances) is sought on issues regarding all areas relevant to drug development, licensing and marketing.

B. Dr. Levy's Broad Pharmaceutical Experience Qualifies Him To Offer His Opinion Regarding the Niacor-SR License

Dr. Levy's broad and in-depth knowledge of the pharmaceutical industry and its practices provides him with unique qualifications to offer his expert opinion concerning the licensing agreement for Niacor-SR. His experience spans all areas relevant to his opinion that the ******* ** and his industry perspective is based on his work with, or for, dozens of pharmaceutical and healthcare companies.

Despite Dr. Levy's extensive relevant experience as a medical doctor and academic, and his two decades of work in the pharmaceutical industry, respondents challenge Dr. Levy's credentials to provide the opinions about which he intends to testify. In its motion, respondents set forth a distorted picture of Dr. Levy's career and qualifications[6] and then argue that Dr. Levy

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6. During Dr. Levy's deposition, respondents' counsel failed to fully examine Dr. Levy's experience at CoreTechs and his positions on the boards of numerous companies, choosing instead to focus on less relevant areas of Dr. Levy's background. For example, they questioned Dr. Levy extensively about a single consumer product that CoreTechs evaluated, rather than (continued...)

is not qualified to testify about the Niacor-SR licensing opportunity because, they contend, he is not expert in cardiology, lipidology and cholesterol, European regulatory affairs, international pharmaceutical marketing, and because he has not attended business school.[7]

Respondents' position that Dr. Levy must be an expert in no less than four different disciplines in order to testify about whether the $60 million payment was for Niacor-SR is not supported by the law. An expert is qualified if he or she has "specialized knowledge" that will assist the fact finder in understanding the evidence or to determine a fact in issue.[8] This element is interpreted liberally.[9] Dr. Levy's general expertise in the pharmaceutical industry and specialized knowledge about pharmaceutical in-licensing arrangements easily qualifies him to evaluate the Niacor-SR licensing deal in this case.[10]

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[6] (...continued)
asking about the dozens of healthcare and pharmaceuticals products Dr. Levy has been involved with during his time at CoreTechs.

[7] Respondents' Mem. at 10-14.

[8] Fed. R. Evid. 702.

[9] *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 741 (3d Cir. 1994); *see also* Fed. R. Evid 702, Advisory Committee Notes (the qualifications of an expert are to be "viewed, not in a narrow sense, but as a person qualified by 'knowledge, skill, experience, training, or education'").

[10] *Diefenbach v. Sheridan Transp.*, 229 F.3d 27, 29-32 (1st Cir. 2000) (affirming qualification of tugboat captain as an expert concerning procedures followed by crews on integrated tugboat/barges even though the witness never spent time on an integrated tugboat/barge); *Elcock v. KMart Corp.*, 233 F.3d 734, 743-44 (3rd Cir. 2000) (affirming qualification of expert with no formal training in the specific field at issue but with experience in a similar field and "substantially more knowledge than an average lay person regarding [the issue in dispute]"); *Tuf Racing Prods., Inc. v. American Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000) ("Anyone with relevant expertise enabling him to offer responsible opinion testimony helpful to judge or jury may qualify as an expert witness")(citations omitted); *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1243-1244 (10th Cir. 2000) (affirming qualification of ergonomics and

Taking the qualifications respondents insists are necessary to opine on whether Schering's $60 million was for Niacor-SR, it is hard to imagine anyone capable of providing reliable expert testimony on this issue. Certainly none of respondents' own licensing experts would come close to qualifying.

- None of respondents' three licensing experts have a medical degree, let alone are cardiologists.[11]

- Upsher's licensing expert, Mr. Bratic, professes no knowledge concerning cholesterol-lowering drugs. He has never held a position at a pharmaceutical company, and therefore, has had no direct responsibility for valuation or in-licensing of pharmaceutical products, no experience in pharmaceutical marketing (let alone oversees), and no experience concerning FDA approval of pharmaceutical products and no experience.[12]

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safety consultant experts even though they had no first hand experience with specific machine at issue); *Rushing v. Kansas City So. Ry. Co.*, 185 F.3d 496, 505–507 (5th Cir. 1999) (affirming qualification of expert audiologist despite his limited experience with outdoor environmental sound measurements at issue); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 856 (3rd Cir. 1990) ("In light of the liberal Rule 702 expert qualification standard, we hold that the district court abused its discretion in excluding portions of [toxicology, microbiology, and PCB exposure experts'] testimony simply because the experts did not have the degree or training which the district court apparently thought would be most appropriate.")

[11] Dr. Levy's medical experience is described in his *curriculum vitae*, in his expert report at page 1 (Attachment B), and in his deposition transcript at 136-143 (Attachment C). The *curriculum vita* provided with respondents' expert reports indicate that none of these experts have received medical degrees. *See generally curriculum vitae* of V. Walter Bratic (Attachment D), *curriculum vitae* of Zola D. Horovitz (Attachment E), and *curriculum vitae* of Kenneth W. McVey (Attachment F). Mr. Bratic's expert report specifically acknowledges that ••••••••••••••• ••••••••••••••••••••• Bratic Expert Report at 4 (Attachment G). Since respondents' expert reports already have been provided to the Court in the context of Complaint Counsel's Motion to Limit or Exclude Duplicative and Improper Expert Witness Testimony, we have not reproduced them in full here.

[12] Bratic Expert Report.

- Schering's expert Dr. Horovitz also has no direct marketing experience. And Schering's other expert, Mr. McVey concedes that he has no direct experience at all with deals anywhere near the size of the Niacor-SR license.[13]

C. Dr. Levy's Relevant Experience Qualifies Him To Testify About How the Major Flaws in Niacor-SR Should Have Affected Schering's Due Diligence

Respondents mischaracterize Dr. Levy's opinion and testimony in arguing that he is not qualified to opine regarding the likelihood of regulatory approval of Niacor-SR. As one example, respondents argue that Dr. Levy's use of a certain measurement for evaluating potential liver toxicity – elevated liver enzymes at the level of 1.5 times the upper limit of normal ("ULN") – is the wrong standard to apply. And from this, they accuse Dr. Levy of drawing "wild conclusions" about the liver toxicity of Niacor-SR and the likelihood of FDA approval.[14] Respondents fail to grasp the significance of Dr. Levy's opinion on this point.

Dr. Levy does not discuss the elevated liver toxicity of Niacor-SR in order to render a specific opinion on whether Niacor-SR would have been approved by the FDA. Complaint counsel's rebuttal expert, Dr. Pitt, a recognized expert in cardiology, will provide that testimony. Rather, Dr. Levy's testimony is for another purpose. It will reinforce the conclusion that

[redacted]

[13] McVey Dep. at 54-56 (Attachment H).

[14] Respondents' Mem. at 2, 16-17.

[redacted]

As Dr. Levy explained in his deposition, the 1.5 ULN measurements was a [redacted] to identify the possibility of liver toxicity which should have alerted anyone reviewing the clinical data to conduct further investigation:

> [redacted][15]

Upsher's medical expert Dr. Keenan shares Dr. Levy's opinion that a 1.5 ULN level for liver toxicity is a matter of concern. At his deposition, Dr. Keenan testified that when liver enzyme elevations go above 1.5 ULN, [redacted][16] The fact that Schering had in its hands the relevant clinical data and ignored

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[15] Levy Dep. at 26.

[16] Keenan Dep. at 94-95 (Attachment I).

the presence of elevated liver enzymes underscores the fundamental deficiencies in Schering's entire due diligence process.

D. Dr. Levy Used Reliable Methods In Reaching His Conclusion That ••••••••

Respondents challenge Dr. Levy's methodology for valuing the Niacor-SR license because he rejects and fails to use the net present value methodology relied upon by some of respondents' experts.[17] As Dr. Levy explained in his deposition, net present value calculations are generally unhelpful in a ••••••••••••[18] Dr. Levy found it was unnecessary to apply that questionable methodology in this case. Based on his review of the record, he was able to apply the principles and methods in which he is an expert to the facts and conclude quite readily that••••••••••

Respondents assert that Dr. Levy's approach must be unreliable because his failure to use a NPV calculation is "contrary to the accepted practice in the pharmaceutical industry." This is a startling argument, to say the least, as Schering's own licensing expert, Mr. McVey, a long-time

[17] Respondents' Mem. at 17-19.

[18] Levy Dep. at 179.

pharmaceutical executive, concedes that he never even thought of conducting a net present value for his expert report in this matter.

[redacted][19]

Mr. McVey then testified that he has [redacted] in his career used a net present value calculation[redacted][20] He went on to agree with Dr. Levy's observation that a NPV calculation is particularly unhelpful[redacted][21] As Mr. McVey explained it: [redacted]

[redacted][22]

II. Dr. Levy's Opinion Rests On His Extensive Experience In The Pharmaceutical Industry And Detailed Review Of The Record, Not On Weighing The Credibility Of Fact Witnesses

Misfiring in its attempt to undermine Dr. Levy's expert qualifications, respondents attack his opinion as inappropriately invading the role of the Court by opining on the credibility of witnesses.[23] Dr. Levy does no such thing. Rather, he takes the facts from the record and applies his extensive expertise in pharmaceutical licensing arrangements to reach an opinion as to whether Schering's $60 million guaranteed payment to Upsher is consistent with a license to

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[19] McVey Dep. at 167-168.

[20] *Id.* at 169.

[21] Levy Dep. at 179.

[22] McVey Dep. at 170-171.

[23] Respondents' Mem. at 21-23.

Niacor-SR, an unapproved product which faced potential regulatory approval obstacles. Based on his expertise and detailed review of the record, Dr. Levy concludes that [redacted] Dr. Levy's expert report includes no accusations or suggestions that there was dishonesty in the Niacor-SR license and he plans to offer no opinions on witness credibility.[24]

In its motion, respondents seem to argue that any expert opinion which contradicts testimony by fact witnesses is impermissible fact finding. This argument goes too far. It is hardly surprising that Dr. Levy's opinion would be inconsistent with the opinions of respondents' experts or with testimony from respondents' employees. This is the reality of the adversarial system. Expert testimony from one side will virtually always bolster, at least implicitly, the credibility of certain witnesses while at the same time casting doubt on the credibility of others. Respondents are simply trying to bootstrap this basic truth of the adversarial system into a reason for excluding the opposing side's expert with whom it disagrees. In *United States v. Rahm*, the Ninth Circuit rejected a similar ploy to exclude expert testimony from a defense expert that

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[24] In his deposition, Dr. Levy did state his personal views as to whether there was dishonesty or untruthfulness by Schering employees, but only in response to repeated questioning by Upsher's counsel. For example, Upsher's counsel asked [redacted] Although Dr. Levy provided his views in response to this line of questioning, such views have nothing to do with the conclusions expressed in his report or as he expects to testify at trial. There was no need for Dr. Levy to probe the motivations of Schering, Upsher, or specific company employees to reach his opinion, because, based on his experience and the record, it is clear that the $60 million could not fairly be considered a licensing fee for Niacor-SR.

would have supported the defendant's story:

> All defense evidence necessarily supported the defendant's "story"; that is its very purpose. . . . The [expert's] testimony certainly would have enhanced Rahm's "credibility" had she taken the stand, but all evidence that supports a defendants actual - or possible - testimony is not credibility evidence. The purpose of Nelson's testimony was not to comment on Rahm's truthfulness in general or with respect to any account Rahm might offer as to how she came to possess the counterfeit currency. Rather, Nelson's testimony was intended to establish Rahm's diagnoses perceptual difficulties, which were relevant to a fact in issue – whether she knew the money was counterfeit. That Nelson's proffered testimony supports the defense theory is the reason it was proffered; it is not a reason for its exclusion.[25]

Dr. Levy's testimony will not comment on the "truthfulness" of any witness, nor is his opinion based on subjective judgments about who is lying and who is not. The fact that Dr. Levy's conclusions about Schering's $60 million payment will support our position and may shed light on the credibility of certain witnesses is "not a reason for its exclusion."[26]

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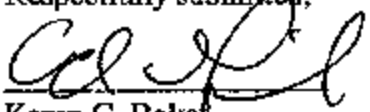
[25] 993 F.2d 1405, 1413 (9th Cir. 1993). *See also Greenwell v. Boatwright*, 184 F.3d 492, 497 (6th Cir. 1999) ("Expert testimony is not inadmissible simply because it contradicts eyewitness testimony"); *U.S. v. Molina*, 172 F.3d 1048 (8th Cir. 1999) (upheld admission of expert testimony on modus operandi of drug dealers even though testimony cast doubt on defendant's credibility by undercutting "innocent companion" defense).

[26] *Rahm*, 993 F.2d at 1413.

* * * * *

For these reasons, we request that the Court deny respondents' joint motion to exclude Dr. Levy.

Respectfully submitted,



Karen G. Bokat
Bradley S. Albert
Seth C. Silber
Andrew S. Ginsburg
Karan R. Singh

Counsel Supporting the Complaint

Dated: January 22, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 22nd day of January, 2002, I caused a copy of the foregoing Public Version of Complaint Counsel's Opposition to Respondents' Joint Motion to Exclude the Expert Testimony of Dr. Nelson L. Levy to be served upon the following person by hand delivery:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused one original and one copy to be served by hand delivery and one copy to be served by electronic mail upon the following person:

Office of the Secretary
Federal Trade Commission
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I caused copies to be served upon the following persons by electronic mail and Federal Express:

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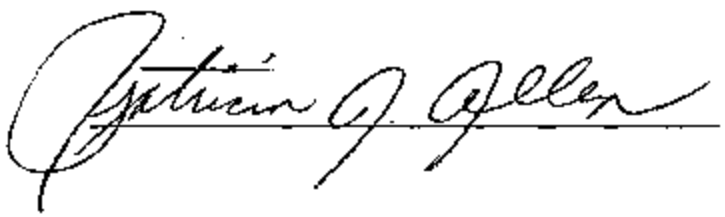

ATTACHMENT A

Nelson L. Levy

1391 Concord Drive
Lake Forest, Illinois 60045
(847) 295 3720
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SENIOR GENERAL MANAGER with unique combination of scientific, clinical, business and managerial experience and perspective. Team builder with very high energy, who leads by recruiting outstanding people, applying creativity to the establishment of aggressive corporate objectives and the optimization of organizational structure and by creating a milieu that stresses "shared influence" and demands and rewards the highest level of professional performance.

PROFESSIONAL EXPERIENCE

CoreTechs Corporation,
Lake Forest, Illinois (1984 - present)

Chief Executive Officer. CoreTechs is a 15 year-old company consisting of two business units. One implements a novel, proactive, value-adding paradigm for the development of early-stage technology; the other provides diverse operating assistance to the health care and biotechnology industries and the investment community serving them.

Recent accomplishments have included:

- Found, evaluated, developed and commercialized over thirty diverse technologies, including pharmaceuticals, diagnostics, devices, software, robotics, chemical and manufacturing processes, consumer products and foods. In most cases, worked on an equity or royalty-sharing basis.

- Helped found and build a $20 million (31% profit) company engaged in the full range of pharmaceutical chemistry, from combinatorial chemistry and drug discovery to process chemistry and large-scale manufacturing. Also markets one of the industry's most highly-regarded compound libraries for high-throughput screening.

- Founded in 1999 a company that is now developing a totally novel treatment for autoimmune disease.

- Founded in 1999 a consumer-product company that already has sales of $600,000, with 30% profitability.

- For a $1.5 billion pharmaceutical company, with R&D groups totalling about 1300 persons, evaluated in detail, restructured and, for eighteen months, directed the total R&D effort, including Discovery, Toxicology, Clinical Research, Pharmaceutics and Regulatory Affairs. After helping to put in place vitalized permanent R&D management, remained as a consultant, reporting to the CEO, for four years. Helped take 3 compounds through development and clinical trials.

- For a $150 million generic pharmaceutical company, helped conceive and build its Ethical Pharmaceutical Division. Assisted with strategic planning and the conception and development of new business opportunities. Helped find, evaluate, license and develop 5 ethical pharmaceutical products. Assisted in the design of an organizational structure and operating paradigm that could accommodate both generic and ethical pharmaceutical strategies.

- For a $19 billion company, assisted with strategic planning, organizational design and the evaluation of acquisition candidates during the establishment and building of its pharmaceutical division.

- For several early-stage companies, provided scientific, clinical and business counsel and leadership. Currently, on the Board of Directors of two public and three private companies and the Scientific Advisory Boards of three public companies.

Fujisawa Pharmaceutical Company, Deerfield, Illinois (1992 - 1993).

The North American subsidiary of Japan's third-largest pharmaceutical company. Sales of $250 million, ~1000 employees, R&D budget of ~$50 million.

President. Responsible for all operations, including marketing, sales, business development, finance, regulatory affairs, MIS and R&D.

- Vitalized a declining, underperforming business. Despite cutting the sales force by 40%, increased monthly sales to highest historical level by extensive re-training of the entire sales force, directing sales efforts to the end-user, rather than the wholesaler, and developing and implementing focused mar(

EDUCATION

B.A./B.S.	Yale University, 1963 Scholar of the House, *Summa cum Laude*, Phi Beta Kappa.
M.D.	Columbia University College of Physicians and Surgeons, 196[illegible]
Ph.D.	Duke University, 1973 (Immunology).

keting programs for each product.

Conceived and implemented a novel management and incentive system for the sales force.

- Integrated financial analysis and P&L management into all elements of the business.

- In-licensed two major pharmaceuticals.

- Created a 10-year strategic plan. The planning itself was an exciting, participative process that involved highly interactive meetings between over 90 senior staff.

- Developed an experienced, highly-capable Regulatory Affairs Department, in order to file 3 NDA's and manage aspects of the company's FDA-mandated validity assessment.

- Brought discipline and accountability to R&D. Led them through a prioritization of their projects and a critical analysis of their data, protocols and personnel. Built lines of communication and cooperation between R&D and marketing, business development and finance. Brought 3 projects to NDA submission.

Abbott Laboratories, Abbott Park, Illinois (1981 - 1984).

Vice President, Pharmaceutical Research. Responsible for all research efforts to discover new pharmaceutical products.

Transformed a moribund research organization, that had not generated a single pharmaceutical product in over 20 years, into a vibrant, productive, self-sustaining body that was highly competitive within the industry.

De-emphasized hierarchy and accented a "walking-around" style of management and leadership.

Showed special ability to communicate complex scientific concepts and information to the non-scientist.

Staff included synthetic, analytical and theoretical chemists, biochemists, pharmacologists, microbiologists, immunologists and systems analysts. Organized into four multidisciplinary divisions: Neuroscience, Cardiovascular Research, Immunoscience/Cell Biology and Anti-Infective Research; plus a core Computer-Assisted Molecular Design division.

Also, developed research strategies for office diagnostics, consumer products and some infant nutritionals and hospital devices.

Functioned as the principal scientific and clinical interface with domestic and international Marketing to develop and implement promotional strategies and with Commercial Development to evaluate in-licensing candidates.

Accomplishments included:

- Six approved NDA's for entirely novel classes of therapy and over $2.5 billion in annual revenues have come from projects conceived, initiated and staffed during my tenure.

- Championed the concept of rational drug design and molecular modeling and built at Abbott one of the industry's leading drug design groups.

- Vitalized the natural product screening program by recruiting some key microbiologists and isolation chemists and by introducing some novel concepts into the assay systems and isolation schemes. Without increasing the staff, the sample throughput was increased over 15-fold, and the isolation rate was increased over 6-fold.

- Organized and orchestrated a highly-successful recruiting effort to bring outstanding scientists to Abbott. Hired 106 staff, including 59 Ph.D.'s, and virtually each Ph.D. hired had been highly sought by the traditional research leaders within the industry. Developed excellent relationships with Academia

- Conceived and implemented a unique organizational structure and management philosophy that maximized the focus upon project objectives, interdisciplinary collaboration and scientific career development. Devised and championed a distinctive Scientific Ladder.

- Built excellent lines of communication and cooperation with the domestic and international Marketing groups.

- Conceived and implemented a series of experiments that provided data upon which were built the principal 1983, 1984 and 1985 promotional campaigns for Abbott's major pharmaceutical products.

- Designed 190,000 square foot laboratory building that incorporates state-of-the-art laboratory and "human ecologic" features.

- Hired eight of the country's most outstanding scientists as consultants in receptor biochemistry, neuropharmacology, microbial biochemistry, molecular modeling, synthetic organic chemistry and analytical chemistry.

Duke University Medical Center, Durham, North Carolina (1973 - 1981).

Associate Professor of Immunology (with tenure). Conducted research on cancer, neurologic diseases and the mechanism whereby the brain may influence the immune response. Taught medical students, graduate students and post-doctoral fellows. Ran laboratory of 20

- 35 persons. Principal investigator on three major research grants with total funding (direct costs) of over $400,000/year.

Accomplishments included:

- Awarded tenure after only three years on the faculty.
- Did seminal research in four disparate fields:
  - Cell hybridization and gene transfer (published world's first paper on gene therapy)
  - Cancer immunology and immunotherapy
  - Virology/immunology in the pathogenesis of endocrine and neurologic disorders.
  - Central nervous system influence on the immune response.
- Published 132 scientific articles.
- Organized and ran an 80-lecture course on Medical Immunology for graduate students and advanced medical students and myself gave 26 of the lectures. The course was one of the most highly-rated courses in the medical school, and I was consistently given outstanding ratings as a teacher.

POST-GRADUATE RESEARCH AND CLINICAL TRAINING

1972 - 73 Resident in Neurology,
Duke University Medical Center

1970 - 72 N.I.H. Special Fellow in Immunology,
Duke University Medical Center

1968 - 70 Research Associate (virology and immunology),
National Institutes of Health
Bethesda, Maryland

1967 - 68 Surgical Intern,
University of Colorado Medical Center
Denver, Colorado

MEDICAL LICENSES AND BOARD CERTIFICATION

Diplomate, The American Board of Allergy and Immunology.

Licensed in North Carolina and Illinois.

REPRESENTATIVE PUBLICATIONS (out of a total of 133)

Levy, N.L. and Notkins, A.L. Virus infections and diseases of the endocrine system. *J. Inf. Dis.* **124**:94, 1971.

Levy, N.L., Snyderman, R., Ladda, R.L. and Lieberman, R. Cytogenetic engineering in vivo: restoration of biologic complement activity to C5-deficient mice by intravenous inoculation of hybrid cells. *Proc. Natl. Acad. Sci. US* **70**:3125, 1973.

Levy, N.L., Scott, D.W. and Snyderman, R. Bone marrow-derived lymphoid cells (B cells): Functional depletion with cobra factor and fresh serum *Science* **178**:866, 1972.

Levy, N.L., Siegler, H.F. and Shingleton, W.W. A multiphase immunotherapy regimen for human melanoma – clinical and laboratory results. *Cancer* **34**:1548, 1974.

Levy, N.L. Specificity of lymphocyte-mediated cytotoxicity in patients with primary intracranial tumor. *J. Immunol.* **121**:903, 1978.

Levy, N.L. Cell-mediated cytotoxicity and serum-mediated blocking: Evidence that their associated determinants on human tumor cells are different. *J. Immunol.* **121**:916, 1978.

Wright, L.L. and Levy, N.L. Generation on infected fibroblasts of human T and non-T lymphocytes with specific cytotoxicity, influenced by histocompatibility, against measles-infected cells. *Immunol.* **122**:2379, 1979.

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PERSONAL INFORMATION:

Married: Louisa Stiles Levy.

Children: 6 sons, aged 15 - 35 years.

Community: Rotary International; Governor's Task Force on Economic Development; Commissioner, Lake County Drainage District; Science Advisory Council of School District 67; Board, Family Service; Secretary, Lake Forest High School Booster Club; Baseball coach for 20 years.

Hobbies: Triathlons, baseball and rock 'n roll.

ATTACHMENT B

United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation
Upsher-Smith Laboratories, Inc.
and American Home Products Corporation

Docket No. 9297

Expert Report

by

Nelson L. Levy, Ph.D., M.D.

August 13, 2001

Restricted Confidential -
Attorney's Eyes Only

The remaining pages of the expert report have been redacted.

ATTACHMENT C

In The Matter Of:

SCHERING-PLOUGH & UPSHER-SMITH
MATTER NO. D09297

NELSON L. LEVY, Ph.D, M.D.
November 20, 2001

For The Record, Inc.
Court Reporting and Litigation Support
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ATTACHMENT D

IN THE UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, Inc. a corporation, and American Home Products Corporation, a corporation	Docket 9297

EXPERT REPORT OF WALTER BRATIC

October 8, 2001

Respectfully Submitted,

Walter Bratic
Vice Chairman and Managing Director
InteCap, Inc.

The remaining pages of the expert report have been redacted.

ATTACHMENT E

United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation,
Upsher-Smith Laboratories, Inc.,
and American Home Products Corporation

Docket No. 9297

Expert Report of Zola P. Horovitz

The remaining pages of the expert report have been redacted.

ATTACHMENT F

United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation
Upsher-Smith Laboratories, Inc.
and American Home Products Corporation

Docket No. 9297
Expert Report of Kenneth W. McVey

The rate charged for review of documents and the preparation of this report was Pounds Sterling 250.00 per hour plus out-of-pocket expenses.

Attorneys' Eyes Only

The remaining pages of the expert report have been redacted.

ATTACHMENT G

IN THE UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, Inc. a corporation, and American Home Products Corporation, a corporation	)	Docket 9297

EXPERT REPORT OF WALTER BRATIC

October 8, 2001

Respectfully Submitted,

Walter Bratic
Vice Chairman and Managing Director
InteCap, Inc.

The remaining pages of the expert report have been redacted.

ATTACHMENT H

In The Matter Of:

SCHERING-PLOUGH & UPSHER-SMITH
MATTER NO. 9910256

KENNETH MCVEY
November 16, 2001

CONFIDENTIAL

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ATTACHMENT I

In The Matter Of:

SCHERING-PLOUGH CORP. & UPSHER-SMITH LABS
MATTER NO. D09297

JOSEPH KEENAN, M.D.
December 7, 2001

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