

GLS Disclosure Webinar

CASE REFERENCE

R. (on the application of National Association of Health Stores) v Secretary of State for Health

Also known as:

National Association of Health Stores v Department of Health

Court of Appeal (Civil Division)

22 February 2005

Westlaw Case Analysis 9 pages

Official Transcript 25 pages

Status:  Positive or Neutral Judicial Treatment

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Case Analysis

Where Reported

[2005] EWCA Civ 154; Times, March 9, 2005; [Official Transcript](#)

Case Digest

Subject: Administrative law **Other related subjects:** Health; Food

Keywords: Administrative decision-making; Consultation; Food safety; Imputed knowledge; Medicine; Ministers; Subordinate legislation

Summary: Knowledge of civil servants who briefed or advised a minister was not to be imputed to the minister if the civil servants did not impart that knowledge. The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 was lawfully made because, although further information could have been put before the minister who signed it, he knew enough to enable him to make an informed judgment and no legally relevant material was left out of account.

Abstract: The appellant association (N) appealed against a decision ([2003] EWHC 3133) dismissing N's challenge to the prohibition of the sale for medicinal purposes of kava kava, a herbal tranquilliser, and its use in foodstuffs. Kava kava was a medicinal product within the meaning of the [Medicines Act 1968](#). After obtaining information and advice, the Secretary of State had made an order under the 1968 Act, namely the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002, prohibiting the sale of kava kava for medicinal purposes. Regulations were also made under the [Food Safety Act 1990](#), namely the Kava-kava in Food (England) Regulations 2002, prohibiting its use in foodstuffs. N had challenged the legislative measures on grounds that the minister had authorised them in ignorance of relevant information and that the prior consultation on the 2002 Order was unlawful because it omitted the possibility of compulsory warning labelling rather than an outright ban. N submitted that the omission of the possibility of requiring warning labelling meant that the 2002 Order should be struck down and that the judge was wrong to hold that in point of law the knowledge of responsible civil servants was the knowledge of the relevant minister. The Secretary of State submitted that the consultation process on the 2002 Order was not flawed.

Held, dismissing the appeal, that to strike down an entire set of regulations because of a curable omission which appeared to have affected nobody would represent a triumph of logic over reason. If an omission could be made good without disrupting the existing, presumptively lawful, text and if the omission appeared to have done no harm, the rule maker should be allowed to cure the defect, [DPP v Hutchinson \[1990\] 2 A.C. 783](#) considered. (2) No consultation had

taken place on the option of introducing compulsory warning labels, but the judge was right that a more drastic expedient, making kava kava a prescription-only drug, was considered and rejected without any subsequent legal challenge, and that in that circumstance the rule maker could not rationally have concluded, whatever the input from consultation, that a warning on the label would be sufficient. Therefore a legally correct approach to consultation would have made no difference to the outcome. (3) The judge had been wrong to hold that knowledge was to be imputed to the minister where civil servants with the relevant knowledge took part in briefing or advising the minister but did not impart that knowledge, [Bushell v Secretary of State for the Environment \[1981\] A.C. 75](#) and *Minister for Aboriginal Affairs v Peko Wallsend Ltd* 162 C.L.R. 24 considered. (4) The object of the 2002 Regulations was so plainly to create a longstop to prevent evasion of the 2002 Order that the only material fact the minister who signed the Regulations needed to know was that the Order had been made by another minister. Therefore the two measures stood or fell together depending on whether the Order was lawfully made. (5) On the evidence the minister who made the Order knew that the Committee on the Safety of Medicines and the Medicines Commission favoured a ban, elements of the statistical data on which that view had been reached, and that a member of the Commission had opposed the ban on the basis that the benefits of kava kava were real and the evidence of toxicity inconclusive. The minister did not know that that member of the Commission was the leading authority on complementary medicine, that he had carried out a meta analysis and how he had spelt out his conclusions. Although the additional information could have been part of the submission to the minister he did not have less information than the law required. He knew enough to enable him to make an informed judgment.

Judge: Sedley, L.J.; Keene, L.J.; Bennett, L.J.

Counsel: For the appellant: Rhodri Thompson QC, Sam Grodzinski. For the respondent: John Cavanagh QC, Jason Coppel.

Solicitor: For the appellant: Irwin Mitchell. For the respondent: Department Solicitor.

Appellate History & Status

Queen's Bench Division

R. (on the application of National Association of Health Stores) v Secretary of State for Health

[\[2003\] EWHC 3133 \(QB\); Official Transcript](#)

Affirmed

Court of Appeal (Civil Division)

R. (on the application of National Association of Health Stores) v Secretary of State for Health

[\[2005\] EWCA Civ 154; Times, March 9, 2005; Official Transcript](#)

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[\[1990\] 2 A.C. 783; \[1990\] 3 W.L.R. 196; \(1991\) 155 J.P. 71; 89 L.G.R. 1; \(1990\) 2 Admin. L.R. 741; \[1991\] C.O.D. 4; \(1990\) 154 J.P.N. 674; \(1990\) 154 L.G. Rev. 872; \(1990\) 140 N.L.J. 1035; \(1990\) 134 S.J. 1041; HL; 1990-07-12](#)

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[\[1981\] A.C. 75](#); [\[1980\] 3 W.L.R. 22](#); [\[1980\] 2 All E.R. 608](#); [78 L.G.R. 269](#); [\(1980\) 40 P. & C.R. 51](#); [\[1980\] J.P.L. 458](#); [\(1981\) 125 S.J. 168](#); HL; 1980-02-07

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162 C.L.R. 24; HC (Aus); 1977-01-01

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[\[2004\] EWCA Civ 49](#); [\[2004\] Q.B. 1044](#); [\[2004\] 2 W.L.R. 1351](#); [\[2004\] I.N.L.R. 268](#); [\[2004\] B.L.G.R. 463](#); [\(2004\) 101\(7\) L.S.G. 35](#); [\(2004\) 148 S.J.L.B. 180](#); Times, February 9, 2004; Independent, February 4, 2004; Official Transcript; CA (Civ Div); 2004-02-02

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[J.P.N. 674; \(1990\) 154 L.G. Rev. 872; \(1990\) 140 N.L.J. 1035; \(1990\) 134 S.J. 1041; HL; 1990-07-12](#)

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Secretary of State for the Home Department v AT

[\[2009\] EWHC 512 \(Admin\); Official Transcript; QBD \(Admin\); 2009-03-20](#)

Followed

R. (on the application of Seabrook Warehousing Ltd) v Revenue and Customs Commissioners

[\[2010\] EWCA Civ 140; \[2010\] S.T.C. 996; Official Transcript; CA \(Civ Div\); 2010-02-25](#)

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[\[2013\] EWCA Civ 1345](#); [\[2014\] Eq. L.R. 60](#); [\(2013\) 16 C.C.L. Rep. 479](#); [Official Transcript](#); CA (Civ Div); 2013-11-06

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The Kava-Kava regulations.

Complementary medicine; Food safety; Ministers powers and duties; Pharmaceuticals; Public health.

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Note on R (National Association of Health Stores) v Department of Health.

Complementary medicine; Food safety; Judicial review; Labelling; Ministers powers and duties; Transit.

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Doc brief (May)

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Doc brief (May)

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[N.L.J. 2005, 155\(7178\), 823-824](#)

Do you have everything you need, minister?

Administrative decision making; Complementary medicine; Food safety; Judicial review; Ministers powers and duties.

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Do you have everything you need, minister?

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Food safety; Judicial review; Ministers powers and duties.

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Documents: [4-138 Committees](#)

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Chapter: Chapter 10 - Judicial Control of Local Authorities, Legal Proceedings by and Against Local Authorities and the Human Rights Act 1998

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Documents: [1-130.8 Implied powers to delegate](#)

C1/2004/0975 & C1/2004/0976, Neutral Citation Number: [2005] EWCA Civ 154
IN THE SUPREME COURT OF JUDICATURE
IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM QUEEN'S BENCH DIVISION
THE ADMINISTRATIVE COURT
MR JUSTICE CRANE
[2003] EWCA 3133 (Admin)

Royal Courts of Justice
Strand, London, WC2A 2LL

Tuesday 22nd February, 2005

B e f o r e:

LORD JUSTICE SEDLEY,
LORD JUSTICE KEENE
AND
MR. JUSTICE BENNETT

- - - - -

THE QUEEN ON THE APPLICATION OF
NATIONAL ASSOCIATION OF HEALTH STORES & ANR

Appellant

- v -

DEPARTMENT OF HEALTH

Respondent

- - - - -

(Transcript of the Handed Down Judgment of
Smith Bernal Wordwave Limited, 190 Fleet Street
London EC4A 2AG
Tel No: 020 7421 4040, Fax No: 020 7831 8838
Official Shorthand Writers to the Court)

Rhodri Thompson QC and Sam Grodzinski (instructed by Messrs Irwin Mitchell) for the
Appellant

John Cavanagh QC and Jason Coppel (instructed by the Solicitor to the Department of
Health) for the Respondent

J U D G M E N T
As Approved by the Court
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Lord Justice Sedley :

1. This appeal is brought, with permission granted by Pill LJ, against the dismissal by Crane J on 19 December 2003 of the claimants' application to strike down two measures adopted under statutory powers by the Secretary of State for Health. The principal measure was an Order¹ made under the Medicines Act 1968 prohibiting the sale for medicinal purposes of kava-kava, a widely used herbal anxiolytic (or tranquilliser) originating in the Pacific region. Under the Food Safety Act 1990 the Secretary of State at the same time made Regulations² banning its use in foodstuffs. In each case the measure was authorised by a minister in the name of the Secretary of State.
2. The principal ground of challenge is that in each instance the minister authorised the measure in ignorance of the relevant fact that prohibition was opposed by a leading psychopharmacological authority, Professor Ernst, on cogent grounds which he had spelt out in a published meta-analysis.
3. It is secondly asserted by the appellants that the prior consultation was unlawful because it omitted the possibility of compulsory warning labelling rather than an outright ban. Thirdly, it is said that the proper consequence of the admitted failure to exempt goods in transit from the food prohibition was the quashing of the Regulations.
4. Wider questions were initially raised – including whether there was on any view enough evidence to justify a ban - but the foregoing are the issues now addressed.

The judgment of the Administrative Court

5. On the first issue, Crane J held that in point of law the knowledge of responsible civil servants was the knowledge of ministers without any requirement that the knowledge be communicated. He found also that in point of fact what one minister, Lord Hunt, who signed the Order, knew about Professor Ernst's views was "adequate and appropriate"; but he was able to make no similar finding about the other minister, Ms Hazel Blears, who signed the Regulation.
6. On the second issue Crane J held that the consultation process under the Medicines Act, but not under the Food Safety Act, was flawed by the omission of the possibility of requiring warning labelling. But he refused to quash the resultant Order because the more drastic option of making kava-kava available on prescription only had been consulted on and rejected, making the rejection of the labelling option a foregone conclusion. By a respondent's notice the Department contests Crane J's initial conclusion that the consultation process was flawed.
7. On the third issue, Crane J accepted that a mandatory exemption in favour of goods in transit had been omitted from the Regulations, and that the error was not severable.

¹ The Medicines for Human Use (Kava-kava) Prohibition Order 2002.

² The Kava-kava in Food (England) Regulations 2002. Separate provision, the subject of a separate and successful challenge, had to be made in Wales.

But he refused to quash them because there was no suggestion that anyone had been adversely affected by the omission and because the Department had offered an undertaking to reconsider the matter. This has now been done, and by virtue of an amending Regulation³ the exemption is in place.

8. Crane J's full and careful judgment, including the text of the statutory provision, can be found at [2003] EWHC 3133 (Admin.).

The legal framework

9. It is sufficient for present purposes to record the following. kava-kava is a medicinal product within the meaning of the Medicines Act 1968. By virtue of s.62(1) ministers may by Order prohibit the sale, supply and importation of such products. Alternatively, s.82 allows them to require such products to be labelled in order, among other things, to convey appropriate warnings. The use of kava-kava in food may also be prohibited by Regulation under s.16 of the Food Standards Act 1990. Alternatively, by virtue of the same section, labelling requirements can be imposed.
10. Both statutes make detailed provision for the obtaining of information and advice before ministers decide whether to introduce any of these restrictive measures.

Medicines

11. The Medicines Commission ("the Commission") is a body of experts established by s.2 of the 1968 Act. Among its functions, under s.3(1), is advising ministers on the exercise of any of their powers under the Act. Under s.4 ministers may set up specialist committees for any purpose within the Act. The committee involved in the present case is the Committee on the Safety of Medicines (CSM). The Commission and the CSM are bodies independent of the Department and of each other.
12. Ministers are required by s.62(3), subject to an exception for emergencies, to consult the appropriate committee, or if there is none the Commission, before making a prohibitory Order. They are also required by s.129(6) to consult "such organisations as appear to them to be representative of interests likely to be substantially affected" by the Order. There is no dispute that the first claimant is such an organisation. This being so, s.62(5) gave it the right, on giving notice, to appear before or to have its written representations referred to the Commission. In such cases, "the Commission shall report their findings and conclusions to the appropriate Ministers and those Ministers shall take that report into account in determining whether to make the order".

Food

13. The Food Standards Act 1999 created the Food Standards Agency (FSA) with the principal objective of protecting public health from risks carried by foodstuffs. The FSA, by choice rather than by law, takes advice from the Committee on Toxicity of

³ The Kava-kava in Food (England) (Amendment) Regulations 2004, SI 2004/455.

Chemicals in Food, Consumer Products and the Environment (COT), a body independent of the Department, with much the same role and status as the CSM.

14. The 1990 Act, as amended, by s.48(4A) requires the Secretary of State to have regard to any relevant advice given by the FSA. By s.48(4) it also requires the Secretary of State to consult organisations representative of potentially affected interests. But by s.48(4B) it allows the Secretary of State to treat consultation by the FSA with such organisations as consultation by himself or herself.

The issues

15. It is convenient to take the issues in reverse order.

Was the omission fatal to the Regulation?

16. It is as well to begin by recognising that to strike down an entire regulation because of a curable omission which appears to have affected nobody, however cogent the case in legal theory for doing so, would represent a triumph of logic over reason.
17. Rhodri Thompson QC, for the appellants, nevertheless contends that it is the correct course. He points out, first, that the Regulation has adversely affected the first claimant's members by damaging their business and the second claimant by restricting her freedom of choice. This misses the point. It is the Regulation, not the omission of the exemption, which has these effects.
18. Arguably more to the point, however, Crane J held that it was impossible, applying *DPP v Hutchinson* [1990] 2 AC 783, to correct the error by blue-pencilling: "The court cannot write in an exemption". But I do not accept that the corollary of this is to strike down the entire instrument. The appropriate corollary, by analogy with blue-pencilling, is to amend it.
19. There will of course be cases in which it is too late, or simply insufficient, to let the rule-maker take this course. *Hutchinson* furnishes a good example: because a lawful instrument would have been "totally different in character" from the impugned one, there was no option but to strike the latter down. But Lord Bridge went on to say that he had concluded, though not without hesitation, "that a rigid insistence that the test of textual severability must always be satisfied if a provision is to be upheld and enforced as partially valid will in some cases ... have the unreasonable consequence of defeating subordinate legislation of which the substantial purpose and effect was clearly within the law-maker's powers ..."
20. This reasoning, although directed in *Hutchinson* to improper inclusions rather than improper omissions, seems to me apposite to the latter as well. If an omission can be made good without disrupting the existing, presumptively lawful, text, and if so far

the omission appears to have done no harm, I see no good reason why, instead of permitting the rule-maker to insert the missing brick, the entire structure should be pulled down.

Was the consultation legally deficient?

21. It is common ground that no consultation took place on the option of introducing compulsory warning labels, even though this was considered within the Department. John Cavanagh QC for the Respondent would if necessary have contested Crane J's holding that this was a justiciable failure of process. His skeleton argument sets out the case against the practicality of such a measure. But he has elected not to pursue it in the light of our indication that, having heard Mr Thompson, we were satisfied that Crane J's subtler answer was sufficient: that a more drastic expedient, making kava-kava a prescription-only drug, was rejected without any subsequent legal challenge. If after what was accepted as being due consultation it was concluded that placing usage and dosage in the hands of qualified medical practitioners was not a sufficient safeguard, the rule-maker could not rationally have concluded, whatever the input from consultation, that a warning on the label would suffice.
22. In spite, therefore, of the important cautions to be borne in mind by the courts against denying relief on the ground that a legally correct approach could have made no difference to the outcome (see in particular *R v Chief Constable of the Thames Valley Police, ex parte Cotton* [1990] IRLR 344 per Bingham LJ, §60), the present case seems to me almost a laboratory example of the proper use of the power. This is because it is not the court's own evaluation – frequently a risky business – but a proper evaluation made by the authorised decision-maker which provides a legal, rather than merely a discretionary, measure of what was possible.

What knowledge does the law impute to Ministers?

23. The next question is altogether more profound. It is not answered, only broached, by the historic decision of this court in *Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560. There the court was presented with an attempt to transpose a familiar doctrine of the law of agency – the rule that one who is delegated cannot himself delegate – into the field of public administration, treating the minister as the Crown's delegate. Lord Greene MR, with his compendious knowledge of public administration, recognised the inappropriateness of the argument and answered it by holding that in law – as the Northcote-Trevelyan reforms had by then firmly established in practice – civil servants acted not on behalf of but in the name of their ministers.
24. *Carltona*, however, establishes only that the act of a duly authorised civil servant is in law the act of his or her minister. It does not decide or even suggest that what the civil servant knows is in law the minister's knowledge, regardless of whether the latter actually knows it. For the novel proposition that it is, Mr Cavanagh founds upon one sentence in Lord Diplock's speech in *Bushell v Secretary of State for the Environment* [1981] AC 75:

“The collective knowledge, technical as well as factual, of the civil servants in the department and their collective expertise is to be treated as the minister’s own knowledge, his own expertise.”

25. It is Mr Cavanagh’s submission that this affords a complete answer, without resort to evidence, to the accusation that Lord Hunt was inadequately informed about Professor Ernst’s views when he signed the Order. The departmental knowledge, which included everything that was material about Professor Ernst and his report, was the minister’s, even if the minister did not in fact know it. This argument, advanced below by Mr Philip Sales, was accepted by Crane J. He held:

72. It follows that information available to officials involved in advising a minister is information that can properly be said to be information taken into account by the minister. It was submitted by Mr. Thompson QC that this would mean that information known to any official in the department can be said to be known to the minister taking a decision. I do not think that follows. If on a challenge to a decision, it were to be asserted that the Secretary of State took into account such information, when in fact no official involved in the matter knew of it, that would in my judgment be an inaccurate assertion. Nor, for example, would it be an accurate assertion if the relevant information was buried in a file but not in fact considered by any official in the matter. However, it does not follow that the court will in the ordinary way investigate whether such an assertion is accurate.

26. In my judgment, and with great respect to Crane J, this part of his decision is unfounded in authority and unsound in law. It is also, in my respectful view, antithetical to good government. It would be an embarrassment both for government and for the courts if we were to hold that a minister or a civil servant could lawfully take a decision on a matter he or she knew nothing about because one or more officials in the department knew all about it. The proposition becomes worse, not better, when it is qualified, as Crane J qualified it and as Mr Cavanagh now seeks to qualify it, by requiring that the civil servants with the relevant knowledge must have taken part in briefing or advising the minister. To do this is to substitute for the *Carltona* doctrine of ordered devolution to appropriate civil servants of decision-making authority (to adopt the lexicon used by Lord Griffiths in *Oladehinde* [1991] 1 AC 254) either a de facto abdication by the lawful decision-maker in favour of his or her adviser, or a division of labour in which the person with knowledge decides nothing and the decision is taken by a person without knowledge.
27. In contrast to *Carltona*, where this court gave legal authority to the practical reality of modern government in relation to the devolution of departmental functions, the doctrine for which Mr Cavanagh contends does not, certainly to my knowledge, reflect the reality of modern departmental government. The reality, subject no doubt to occasional lapses, is that ministers (or authorised civil servants) are properly briefed about the decisions they have to take; that in the briefings evidence is distinguished from advice; and that ministers take some trouble to understand the evidence before deciding whether to accept the advice. I will come later in this judgment to the critical question of how much of the evidence the minister needs to know; but I cannot believe that anybody, either in government or among the electorate, would thank this court for deciding that it was unnecessary for a decision-maker to know anything material before reaching a decision.

28. Four years after *Bushell* was decided, the High Court of Australia had before it an issue akin to the issue before us. A minister had made an order affecting land rights in ignorance of a potentially crucial fact. The fact was known, however, within his department. It is of interest that the minister's counsel, David Bennett QC (now S-G), one of Australia's leading constitutional lawyers, did not attempt to advance the argument which has been advanced by Mr Cavanagh. He contended only that the minister could lawfully delegate fact-finding to officials, and that there was no evidence that the material fact had been overlooked at official level: in other words, he sought to refine *Carltona* into a doctrine of split or partial delegation.
29. The High Court rejected this endeavour. Gibbs CJ said:
- “Of course the Minister cannot be expected to read for himself all the relevant papers that relate to the matter. It would not be unreasonable for him to rely on a summary of the relevant facts furnished by the officers of his Department. No complaint could be made if the departmental officers, in their summary, omitted to mention a fact which was insignificant or insubstantial. But if the Minister relies entirely on a departmental summary which fails to bring to his attention a material fact which he is bound to consider, and which cannot be dismissed as insignificant or insubstantial, the consequence will be that he will have failed to take that material fact into account and will not have formed his satisfaction in accordance with law”
30. Mason J (as he then was) pointed out that what was being proposed was that “the minister had power to delegate part of his decision-making function ... to his department, and that he exercised this power by splitting the function, leaving his staff to decide what facts or matters would be taken into account.” Any delegation, he went on to point out, must first be lawful and secondly be shown to have been made. He made it clear that in that case (as in this) the issue was whether the decision-maker had omitted a consideration which was in the obligatory class of relevance.
31. The High Court was unanimous in rejecting the argument, both on principle and from convenience, that the minister could decide without actually knowing something which bore the requisite degree of relevance to his decision. I will come below to the valuable remarks of Brennan J on the content of the ministerial obligation.
32. In the light of this significant Australian decision one comes back to what Lord Diplock said in *Bushell*. The full passage reads:
- “ What is fair procedure is to be judged not in the light of constitutional fictions as to the relationship between the minister and the other servants of the Crown who serve in the government department of which he is the head, but in the light of the practical realities as to the way in which administrative decisions involving forming judgments based on technical considerations are reached. To treat the minister in his decision-making capacity as someone separate and distinct from the department of government of which he is the political head and for whose actions he alone in constitutional theory is accountable to Parliament is to ignore not only practical realities but also Parliament's intention. Ministers come and go; departments, though their names may change from time to time, remain. Discretion in making administrative decisions is conferred upon a minister not as an individual but

as the holder of an office in which he will have available to him in arriving at his decision the collective knowledge, experience and expertise of all those who serve the Crown in the department of which, for the time being, he is the political head. The collective knowledge, technical as well as factual, of the civil servants in the department and their collective expertise is to be treated as the minister's own knowledge, his own expertise."

33. In my judgment *Bushell* is not authority for what Mr Cavanagh seeks to derive from it. It is a decision about due process – specifically, about what fairness requires where new material which emerges between the report to the minister and his decision is digested departmentally. Lord Diplock's point is that the departmental advice is part of the ministerial decision, not of the inspector's report. It is an element in the minister's thinking. It was not argued before the House, and their Lordships were not invited to decide, that the minister could reach his decision in ignorance of a relevant factor so long as it was known within his department. The question was whether what was known to the department ought to have been made available to the objectors. This is why in *Peko-Wallsend* Brennan J was able to cite the material passage from *Bushell* in support of his proposition (at 66) that "if ... the validity of the minister's decision depends upon his having had regard to the salient facts, his ignorance of the facts does not protect the decision".
34. I do not understand the decision of this court in *R v Secretary of State for Education, ex parte S* [1995] ELR 71 to have done more than apply *Bushell* in the sense I have ascribed to it. Russell LJ at 78 accepted the submission that, provided the issue is not a new one, ministers are entitled to consider in-house advice on it without first disclosing the advice for comment. Peter Gibson LJ, whose knowledge of this field is very great, described (at 85) "the practical reality... that the Secretary of State would call on the considerable expertise within his department *to assist him in making up his mind*". The words I have italicised help Mr Cavanagh not at all.
35. The courts have had from time to time to question the apparent breadth of Lord Diplock's dictum. In *Best v Secretary of State for the Environment* [1997] EWHC Admin 226 counsel for an objector in a planning case based upon it a submission that the contents of an incoming letter lying in the Department's postroom were imputedly known to the Secretary of State. The deputy High Court judge, Mr. Lockhart-Mummery QC, generously described the submission as having an air of unreality. Mr Cavanagh, recognising this, falls back upon a limitation of material knowledge to that possessed by "civil servants who have responsibility for receiving the information, considering it and advising the minister thereon". This was how it was argued for the minister and accepted by the deputy judge in *Best*, so that at least the contents of the postroom were exempted from the departmental fund of knowledge; but for reasons I have given in paragraph 26 above it makes the respondent's position more, not less, problematical.
36. Implicitly acknowledging this, Mr Cavanagh submitted that the *Bushell* doctrine involves neither actual nor even imputed knowledge on the minister's part. In a sense which he was content to call metaphysical, the knowledge of responsible civil servants *was* the knowledge of the minister because the department was a single entity. The nearest Mr Cavanagh was able to come to citing binding authority for this view was Lord Hoffmann's remark, explaining the *Bushell* dictum, in *R (Alconbury*

Ltd) v Secretary of State for the Environment [2003] 2 AC 295, §127, that “the process of consultation within the department is simply the Secretary of State advising himself”. But this, it is to be noted, followed a passage (§126) in which Lord Hoffmann described the departmental decision-making processes in this way:

“These contain, on the one hand, elaborate precautions to ensure that the decision-maker does not take into account any factual matters which have not been found by the inspector at the inquiry or put to the parties and, on the other hand, free communication within the department on questions of law and policy, with a view to preparing a recommendation for submission to the Secretary of State or one of the junior ministers to whom he has delegated the decision.”

None of this is grist to Mr Cavanagh’s mill.

37. The serious practical implication of the argument is that, contrary to what the decided English cases take for granted, ministers need know nothing before reaching a decision so long as those advising them know the facts. This is the law according to Sir Humphrey Appleby. It would covertly transmute the adviser into the decision-maker. And by doing so it would incidentally deprive the adviser of an important shield against criticism where the decision turns out to have been a mistake.
38. The only authority Mr Cavanagh was able to produce which appeared to chime with his argument was a decision of Lord Clyde, sitting in the Outer House of the Court of Session, in *Air 2000 v Secretary of State for Transport (No 2)* [1990] SLT 335. Advice from the Civil Aviation Authority which by statute the Secretary of State was required to consider had been seen not by him but by an interdepartmental working party which advised him. Lord Clyde cited *Carltona* for the uncontroversial proposition that “what is done by his responsible official is done by [the minister]”. However, while rejecting as “too extreme” a submission that the mere physical delivery of the advice to the department was sufficient, Lord Clyde accepted that “if it is given to an official who has responsibility for the matter in question, that should suffice”. If by this Lord Clyde meant that such receipt would amount in law to consideration by the Secretary of State, I would respectfully disagree. For the reasons I have given, it would be incumbent on such an official to ensure that either the advice or a suitable précis of it was included in the submission to the minister whose decision it was to be.

Did the Ministers know enough to sign the measures?

39. Three initial matters need to be mentioned. One is the status of executive agencies in the system of departmental government. The second is the relationship between the Medicines Order and the Food Regulation. The third is the adduction of secondary evidence of the information placed before ministers rather than production of the submission itself.

Executive agencies

40. It was accepted by the claimants before Crane J that the Medicines Control Agency (since April 2003 the Medicines and Healthcare Products Regulatory Agency, abbreviated to MHRA), an executive agency, was part of the defendant Department, so that its officials stood in the same relation to the Minister as departmental civil servants. This agency, as I understand it, was created and recreated under prerogative powers. By contrast, the Food Standards Agency (FSA) is the creature of s.1 of the 1999 Act. Other advisory bodies mentioned earlier in this judgment (the Commission, the CSM, the COT) are on any view independent of government.
41. The constitutional status of individual executive agencies is not necessarily an easy question, since, as I have indicated, they can be brought into being under more than one power and since they will have a variety of forms and functions. In *R v Home Secretary, ex parte Sherwin* (DC, 16 February 1996, unreported) it was accepted that the Benefits Agency was part of the Department of Social Security, having been set up under the prerogative power pursuant to the Prime Minister's statement of 18 February 1988. But the same may not be true of, for example, the FSA. One obvious test will be whether the executive agency possesses legal personality, but this may not be the only question: see Bradley and Ewing *Constitutional and Administrative Law* (13 ed.) 291-4, and the Cabinet Office website "Executive agencies and non-departmental public bodies". We have not been called upon to decide the point, but its potential difficulty needs to be noted.

The medicines Order and the food Regulation

42. There was an initial issue about what was known to Ms Hazel Blears, the minister who signed the food Regulation. In sum, the evidence did not suggest that she had been briefed at all about the Ernst review. But Mr Thomson, on reflection, accepted the court's suggestion that the object of the Regulation was so plainly to create a longstop to prevent evasion of the medicines Order that the only material fact Ms Blears needed to know was that the medicines Order had been made by another minister.
43. This being so, it became common ground that the two measures stood or fell together, the outcome depending on whether the medicines Order was lawfully made.

The use of secondary evidence

44. In the course of exchanging evidence, a witness statement was made by Dr June Raine, director of the post-licensing division of the MHRA, which contained the following paragraphs:

11. Second, the Claimants appear to assume – without, I might say, any justification – that the Medicines Commission advice was the only material placed before Lord Hunt, the Minister who decided that the Order should be made. The MHRA has thus far not specified exactly what material went before the Minister, for the principal reasons that that is irrelevant as a matter of law, and, as a matter of practice, Government departments do not disclose the contents of their submissions to ministers. There is generally no practical

need to do so, as Claimants do not seek to maintain that there is a distinction to be drawn between a minister and his or her civil servants.

12. However, that point has been taken in this case and, whilst the MHRA would not wish to be seen to be setting any precedent in this regard, it does wish to assist the court by disclosing the material details of what was put before Lord Hunt. The submissions to him included:

- the advice from the CSM and the Medicines Commission.
- an explanation of the current status of the adverse reaction reports, to the effect that the MHRA was aware of 69 adverse reaction reports of hepatotoxicity suspected to be due to kava-kava, 4 of which were fatal and 6 required liver transplants. It was also explained that the causal relationship had been assessed for these cases and had been broken down into 15 probable, 30 possible, 19 unassessable and 5 considered unlikely to be related to kava-usage. (The Claimants' allegation in §134 that the latter breakdown was not disclosed to Lord Hunt is also misplaced).
- an explanation that Professor Ernst, a member of the Medicines Commission, opposed the prohibition and had contributed to the lengthy discussion at the Commission's meeting, but that ultimately the Commission had reached the view that an Order was justified. Professor Ernst's objections to the prohibition of kava-kava were summarised.

13. Lord Hunt was not provided with a copy of the Review (or indeed of any other primary scientific materials), but the Review was part of the body of evidence taken into account by Mr Woodfield of the MHRA when formulating his submission to Lord Hunt, which recommended that an Order should be made.

45. At trial, Mr Thompson applied for production of the ministerial briefing itself, but Crane J after hearing submissions refused it. He said:

Disclosure

74. I am prepared to accept that if there is reason to doubt the assertion that a particular factor has been taken into account, the Court may exceptionally inquire further into the decision-making process within a department. Moreover, if, as here, the department chooses to reveal part of the decision-making process, the Court will have regard to such evidence. Such evidence may give rise to questions calling for an answer. Only exceptionally is it appropriate for the Court to exercise its power to order disclosure. That is consistent with the words of Lord Clyde in *Air 2000 Ltd v Secretary of State for Transport (No.2)* 1990 SLT 335 at 341, of the Divisional Court in *R. v Secretary of State for Foreign and Commonwealth Affairs, ex parte World Development Movement Ltd.* [1995] 1 WLR 386 and of the Court of Appeal in *R. v Secretary of State for Education, ex parte S* [1995] ELR 71.

75. Ms Raine has explained how far Professor Ernst's views were considered by the civil servants and how far those views were passed on to Lord Hunt. In my judgment her evidence on these matters is more than adequate for the purposes of the present proceedings. There is no reason to doubt what she says on these matters. I saw and still see no good reason for ordering further disclosure.

46. Permission was not sought to appeal against this aspect of the decision. This court, however, raised it with counsel because it seemed to all three of us that we were being required to ignore the best evidence rule by being made to rely on a second-hand account of a document of which the original was available.
47. Mr Cavanagh confirmed that there was no question of public interest immunity. (If there had been, of course, secondary evidence would have been as inadmissible as primary evidence.) It was simply that it was contrary to policy to make voluntary disclosure of ministerial briefings. If that is so, then it seems to me entirely inconsistent to tender and rely on a secondary account instead. The courts would not allow a private litigant to do this, and in a legal system in which the state stands before the courts on an equal footing with its citizens there is no good reason to allow government to do it. Mr Cavanagh, having taken instructions, told us with complete candour that that if we were to order disclosure it would not be problematical, either because of volume or because part of the briefing had been oral.
48. However, having invited Mr Thompson to apply out of time for permission to appeal against this limb of Crane J's judgment, and having heard argument on it, we decided not to call for the written submission to the minister. We reached this decision on the single ground that both parties had expressed themselves content to take Dr Raine's summary as establishing a state of fact which I will set out later. For Mr Thompson, the reason was that he considered that this summary gave him the ammunition he needed for his challenge, and that for all he knew the document itself might diminish its effectiveness. For Mr Cavanagh, the reason was his instructing department's policy.
49. But for this tactical consensus we were in agreement that we would have required the briefing to be produced. The best evidence rule is not simply a handy tool in the litigator's kit. It is a means by which the court tries to ensure that it is working on authentic materials. What a witness perfectly honestly makes of a document is frequently not what the court makes of it. In the absence of any public interest in non-disclosure, a policy of non-production becomes untenable if the state is allowed to waive it at will by tendering its own précis instead.
50. We do not have to decide what would have been the right outcome if there had been a complete refusal to say anything about what the minister was told; but it may be that the understanding of the law summarised by Crane J (in his paragraph 74, quoted above) reflects an approach which today is unnecessarily protective of government, and of government alone, in public law proceedings brought not as of right but with permission which will have been given only in the light of the state's initial response.

Did the Minister leave relevant matter out of account in deciding to make the Order?

51. I have set out in paragraph 44 above Dr Raine's account of what the minister, Lord Hunt, was told by way of briefing. On the basis of it and of the concession I have described above, we are invited to approach what is now the critical issue on the agreed footing that Lord Hunt was not told of Professor Ernst's special expertise in psychopharmacology; nor that Professor Ernst had just completed a meta-analysis of the scientific evidence about kava-kava; nor the conclusions of that review.
52. These facts need a little expansion. A meta-analysis is in an important sense the highest level of analysis of scientific data. The adverse reaction reports, which did not rank for inclusion in the meta-analysis, lay in a small compass – fewer than 70 reported cases, of which fewer than 20 were thought, by those reporting them, to be probably rather than possibly or speculatively linked to kava-kava use. But among the 'probable' cases were a few in which the outcome had been fatal. Because these data were anecdotal rather than epidemiological, and because no independent aetiological research established a biological connection, the link between the use of kava-kava and the death or acute illness of individual patients was at highest inferential and at lowest speculative.
53. Professor Ernst's meta-analysis was usefully prefaced by a synopsis and a summary of conclusions. These read as follows:

Synopsis

Systematic literature searches were conducted to assess the evidence for and against the effectiveness of kava extract for treating anxiety. Twenty-one potentially relevant double-blind, placebo-controlled randomised clinical trials were identified. Eleven trials met the inclusion criteria. The meta-analysis of six trials suggests a significant differential treatment effect for the total score on the Hamilton Anxiety Scale in favour of kava extract. Adverse events reported in the reviewed trials were mild, transient and infrequent. These data imply that kava extract is superior to placebo as a symptomatic treatment of anxiety. Further and more rigorous investigations into the effectiveness and safety of kava extract would be welcome.

Reviewers' conclusions

Compared with placebo, kava extract appears to be an effective symptomatic treatment option for anxiety. The reviewed data suggest that kava is safe for the short-term treatment. Given the recent reports of adverse events, kava should not be taken concomitantly with hepatotoxic drugs or over longer periods of time. Further rigorous investigations, particularly into the safety profile of kava are required.

54. The discussion section of the report contained the following paragraphs:

Discussion

Collectively, these results suggest that, compared with placebo, kava extract is an effective treatment option for anxiety. The effect, however, lacks a degree of robustness as indicated by the sensitivity analyses and is based on a relatively small sample. Nonetheless, the

reviewed trials which could not be included in the meta-analysis support the findings and suggest that kava is beneficial for patients with anxiety. Thus, the reasonable overall agreement between RCTs suggests validity of the overall result. In addition, all of the excluded studies report results indicating anxiolytic effects of kava extract and kavain, which is also corroborated by the results of previous reviews (Singh 1998; Weber 1994; Chrubasik 1997; Hansel 1996). However, more rigorous trials investigating the effectiveness and safety of kava extract would be welcome. None of the trials reported any hepatotoxic events. Six of the reviewed trials (Gastpar 2002; Geier 2002; Lehl 2002; Malsch 2001; Volz 1997, Warnecke 1991) measured liver enzyme levels as safety parameters and report no adverse events.

At the time of writing (August 2020) 68 documented cases of suspected kava hepatotoxicity were on record worldwide. In many of these instances, the exact nature of the extract was not specified. It is clear, however, that all types of extract and synthetic kavain are implicated. In the vast majority of these cases other drugs – some with known hepatotoxicity – were taken concomitantly, a fact, which considerably complicates causal attribution. Similarly, in many of these cases reports no data for alcohol consumption or viral infection are provided. Then problems typically occurred 2 to 3 months after kava intake; in some cases the length of kava use was not known. The adverse events ranged from mere transient elevations of liver enzymes to severe (often cholestatic) hepatitis and fulminant liver failure. In most instances the patients seemed to have recovered fully after discontinuation of kava. However, 6 patients required liver transplants and 3 patients died. Reliable incidence or prevalence figures are not currently available. In our own systematic review of the data, two drug monitoring studies of kava were located (Stevenson 2002). They included a total of 7078 patients taking kava extract equivalent to 105 mg to 240 mg kavalactones per day for 5 to 7 weeks. In these studies no cases of hepatotoxicity emerged. Two other postmarketing surveillance studies, including 1673 patients who received kava extract equivalent to 120 mg kavalactones daily for 5 weeks (Spree 1992) and 2944 other patients who received 400 mg kavain daily for 4 weeks (Unger 1988) corroborate this and report no hepatotoxic events. No plausible mechanism for the alleged hepatotoxic effects of kava has so far been identified. The question therefore remains whether the frequency of liver damage in kava users differs significantly from that of non-kava users.

Limitations of this meta-analysis pertain to the citation tracking and its potential incompleteness. Although strong efforts were made to locate and retrieve all trials on the subject, it is conceivable that some were not uncovered. The distorting effects on systematic reviews arising from publication bias and location bias are well-founded (Easterbrook 1991; Egger 1998). This includes suggestions that positive findings may be overrepresented in complementary medicine

journals (Ernst 1997; Schmidt 2001) and that these journals favour positive conclusions at the expense of methodological quality (Pittler 2000). In addition, there is evidence for the tendency of positive findings to be published in English language journals (Nieminen 1999) and for some European journals to not be indexed in major medical databases (Egger 1997). Therefore the possibility of treatment effects to be exaggerated exists.

Other pharmacological options include antidepressants and benzodiazepines. The latter, however, may cause adverse events such as sedation, amnesia, development of tolerance and carry an increased risk of road-traffic accidents (Barbone 1998; Moore 1998; O'Neill 1998). Comparative studies suggest the absence of significant differences between benzodiazepines and kava or kava extract (Lindenberg 1990; Woelk 1993) in terms of effectiveness. More equivalence studies are needed, not least to define the relative risks of both approaches.

55. The Ernst report was not ready in time for circulation with the other papers prior to the Commission's meeting on 7 November 2002, but the MHRA considered it and concluded that it did not alter their view in favour of a ban. At the Commission's meeting, however, Professor Ernst was present and presented his findings. Following almost an hour's discussion, the Commission voted heavily in favour of a ban. It thereafter submitted a short statement conveying its collective advice to the Secretary of State. This was annexed to the briefing paper submitted to the minister.
56. Even on the view of the law urged on behalf of the Secretary of State, the Commission's knowledge could not be regarded as the minister's. Nor could its conclusion lawfully be adopted without more by the minister. The question is therefore whether enough in addition to the Commission's advice was placed before him.
57. On the evidence we have, then, the minister knew the following:
 - That the CSM and the Commission favoured a ban.
 - The elements of the statistical data upon which this view had been reached.
 - That Professor Ernst, as a member of the Commission, had opposed a ban because the benefits of kava-kava were real and the evidence of toxicity inconclusive.

What he did not know was

- That Professor Ernst was the leading authority on complementary medicine.
- That he had carried out a meta-analysis, the most elaborate form of scientific survey of data of this kind.

- How Professor Ernst had spelt out his conclusions.

58. The policy of taking the decisions with which we are concerned at ministerial level reflects the fact not only that any restriction or ban on the sale of a product does economic damage and restricts choice, but also that there are conflicts of economic interest between, in particular, the pharmaceutical industry and the health foods market which may have a bearing on both the input and the output of scientific inquiry into product safety. The policy thus recognises the importance of a disinterested decision made at high level with the benefit of the best available information. In this situation the Commission's practice of reporting in unitary form the outcome of what may in many cases be a close-run debate made it more, not less, appropriate that the minister should know that as distinguished an authority as Professor Ernst had dissented, and on what grounds.
59. It might therefore have been very much better if the additional information noted above had been part of the submission to the minister. It would have added little to his workload, and it would have enabled him to see more precisely why the case against a ban was a cogent one. In the course of argument Mr Thompson tried, without success because it is so anomaly-ridden, to rely on the legal provision for selling tobacco, a known killer, subject merely to warnings. But one has only to open the family medicine chest to find everyday drugs, most of them available on prescription only but some available over the counter, with leaflets warning of side-effects some of which are comparable in gravity to those tentatively attributed to kava-kava. I am perfectly willing to accept that the minister's decision on kava-kava could have gone either way.
60. But what in the end I am unable to accept is that the minister had less information than the law required. The test is the familiar public law test: was something relevant left out of account by him in taking his decision? It is not, with respect to Mr Cavanagh, the different question whether his decision was vitiated by an error of fact (as to which see now *E v Home Secretary* [2004] QB 1044).
61. I have found Brennan J's judgment in *Peko-Wallsend* particularly helpful here. He said (at 61):

“A decision-maker who is bound to have regard to a particular matter is not bound to bring to mind all the minutiae within his knowledge relating to the matter. The facts to be brought to mind are the salient facts which give shape and substance to the matter: the facts of such importance that, if they are not considered, it could not be said that the matter has been properly considered.”

Then at 64:

“[The] decision cannot be attacked on the ground that the minister has not given sufficient *weight* to detriment, but it can be attacked if the minister fails to have regard to detriment. The minister may deny any weight to detriment, but only if he has first had proper regard to that matter.”

And at 65:

“The department does not have to draw the minister’s attention to every communication it receives and to every fact its officers know. Part of a department’s function is to undertake an evaluation, analysis and précis of material which the minister is bound to have regard to or to which the minister may wish to have regard in making decisions.... The consequence ... is, of course, that the minister’s appreciation of a case depends to a great extent upon the appreciation made by his department. Reliance on the departmental appreciation is not tantamount to an impermissible delegation of the ministerial function. A minister may retain his power to make a decision while relying on his department to draw his attention to the salient facts..”

62. Given the constitutional position as this court now holds it to be, a minister who reserves a decision to himself – and equally a civil servant who is authorised by him to take a decision - must know or be told enough to ensure that nothing that it is necessary, because legally relevant, for him to know is left out of account. This is not the same as a requirement that he must know everything that is relevant. Here, for example, much that was highly relevant was appropriately sifted by the Commission in formulating its advice and then distilled within the department in order to make a submission to the minister which would tell him what it was relevant (not simply expedient or politic) for him to know. What it was relevant for the minister to know was enough to enable him to make an informed judgment. This centrally included the Commission’s advice and the reasons for it. It also included the fact of Professor Ernst’s opposition and the essential reasons for it. All this he had.
63. Did the legally relevant material go wider than this? In *CREEDNZ Inc v Governor General* [1981] 1 NZLR 172 Cooke P drew the distinction, which our courts had previously failed to draw, between things which are so relevant that they must be taken into account and things which are not irrelevant and so may legitimately be taken into account. It is axiomatically only a failure to take into account something in the former class that will vitiate a public law decision. Whether something falls into this class is typically a mixed question of law and fact, although – as with the statutory requirements to consult the CSM and to take account of the Commission’s findings – it may be a matter of pure law.
64. Here, while – as I have said – it might have been better had a certain amount more been drawn to the minister’s attention, I am unable to hold that the three matters omitted from the briefing were things which either the statutory purpose or the nature of the issue before the minister made so relevant that a lawful decision could not be taken in ignorance of them. They are all things which undoubtedly enhanced the case against a ban, but that is not the test. Their context is a departmental submission conveying among other things a view reached by the Commission after a debate initiated by Professor Ernst on his newly published meta-analysis. Professor Ernst’s standing and the quality of his paper will have been of considerable significance to the Commission. For the minister, by contrast, it will have been part of the background and not, in my judgment, something he had to know in order to take his decision.
65. The decision not to put before the minister the exact reasons given by Professor Ernst for his conclusion seems to me closer to the borderline. It is one thing for the minister to know that a member of the Commission was against a ban. It is arguably another to read in his own words why. But among the accepted facts is that the submission summarised Professor Ernst’s objections to a ban. In the absence of a copy of the

submission itself there is no good reason to suppose that the summary did less than justice to the objections, and the gap closes.

The European dimension

66. I have left until last, in spite of Mr Thompson's submission that it should come first, the European jurisprudence on the level or intensity of consideration owed by member states when considering prohibitions of the present kind. He criticises Crane J for having overlooked it.
67. The EU has a clear interest under the Treaty in national restrictions on the sale and movement of goods. The ECJ accordingly requires member states to limit marketing bans, which are the most drastic form of measure, to cases where "the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the adoption" of the measure in question: *Commission v Denmark* [2003] ECR I-9693, §48. In *Alpharma v Commission* [2002] ECR II-3495 the Court made it clear that high-grade scientific assessment of risks was "an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures". Subject to these procedural protections, the precautionary principle not only permits but requires states to put public health and safety before economic interests where specific risks are established.
68. In *Artegodan v Commission* [2002] ECR II-4945 the Court of First Instance stressed that the expert body – the CPMP - reporting to member states must "refer to the main reports and scientific expert opinions on which it relies and ... explain, in the event of a significant discrepancy, why it has departed from the conclusions of the reports or expert opinions supplied by the undertakings concerned. That obligation is particularly strict in cases of scientific uncertainty."
69. What is significant about *Artegodan* is that the CPMP stood in the position of an expert adviser, not a decision-maker. The decision therefore offers some support to Mr Thompson in his resistance to Mr Cavanagh's primary submission that decision-makers need not know the material facts. It also, together with the other cases I have mentioned, supports the proposition that the decision-making process must be as well-informed as science permits. (One notes that Mason J, setting out the requirements of the common law, said exactly the same in *Peko-Wallsend*, ante, at 45.) But none of these principles, all of which I unhesitatingly accept, tells us how much of the data must be put before the decision-maker. The jurisprudence is consistent with devolution of the functions of analysing, sifting, summarising and advising; but how the presentation and assessment of the best available scientific data and opinion – which in the present case plainly included Professor Ernst's meta-analysis and conclusions - is to be carried out has to remain a matter of judgment and practice from case to case. Where the law steps in is, first, by insisting that it is the designated decision-maker who must make the final decision, and secondly by ensuring, if an issue arises about it, that in one form or another the decision-maker knows enough to make a genuine decision as opposed to merely accepting advice.

Conclusion

70. For reasons which differ in significant part from those of Crane J, I would dismiss this appeal.

Lord Justice Keene:

71. I agree and wish to add only a few comments of my own on the issue of the extent of the minister's knowledge, because of its importance in administrative law. It is vital to distinguish between two situations. The first is where a civil servant makes a decision in the name of his government minister, often a Secretary of State, where a statute has vested the decision – making power in the Secretary of State. In such a situation the *Carltona* case establishes that the civil servant acts, and is entitled to act, in the name of the minister.
72. The second situation is where a minister is himself actually the decision-maker. *Carltona* says nothing about the imputing of the knowledge of relevant facts to the minister merely because those facts are known to one or more of his civil servants, no matter how senior. Nor in my judgment does the passage from Lord Diplock's speech in *Bushell* establish any such proposition. That was a case concerned with whether or not it was unfair for a government minister to receive advice and information from his civil servants without it being disclosed to those who had objected at a public inquiry and without it being tested through the inquiry processes. *Bushell* was not dealing with whether a government minister is assumed to know what his civil servants know when the issue is whether he has taken relevant matters into consideration in arriving at his own personal decision.
73. Where the decision is in truth one taken personally by a minister, the normal principles of administrative law will apply, so that on a challenge by way of judicial review the court will consider whether the minister as decision-maker has taken into account irrelevant considerations or failed to take into account relevant ones. Where the decision-maker is in fact a civil servant, the same principles apply to that civil servant's decision, albeit the discussion will nominally refer to "the Secretary of State". This approach accords with the decision of the High Court of Australia in the *Peko-Wallsend* case. As Gibbs CJ said in his judgment in that case at pages 30 – 31:

"Of course the Minister cannot be expected to read for himself all the relevant papers that relate to the matter. It would not be unreasonable for him to rely on a summary of the relevant facts furnished by the officers of his Department. No complaint could be made if the Departmental officers, in their summary, omitted to mention a fact which was insignificant or insubstantial. But if the Minister relies entirely on a departmental summary which fails to bring to his attention a material fact which he is bound to consider, and which cannot be dismissed as insignificant or insubstantial, the consequence will be that he will have failed to take that material fact into account and will not have formed his satisfaction in accordance with law."

The judgment of Brennan J reflects the same analysis: see pages 65 to 66. In my judgment those passages are an accurate statement of the position in English law as well.

74. The implication of Mr Cavanagh's submission, as he frankly acknowledged, is that a minister who *personally* makes a decision of this kind can do so validly, even though in complete ignorance of an important and highly relevant consideration, so long as his civil servants know about it. I cannot accept that that is the law. To take an example discussed in argument, it would mean that the Secretary of State could personally decide that planning permission should be granted for a major housing development in the approved Green Belt without being aware of the Green Belt status of the land in question. If that were held to be a valid and *intra vires* decision by him, it would negate basic propositions of English administrative law established well before *Associated Provincial Picture Houses Limited v. Wednesbury Corporation* [1948] 1 KB 223.
75. If, then, one is concerned with the state of the minister's own knowledge, were the decisions in the present case rendered invalid by some relevant matter being left out of account? As a matter of principle, one needs to recognise that there are degrees of relevance. Sedley LJ refers in his judgment to the decision of Cooke J in *CREEDNZ Inc. v. Governor-General*, a case which deserves to be better known. The proposition found therein that, while some matters may properly be taken into account by the decision-maker, not all of those will be ones which the decision-maker is bound to take into account, was approved by the House of Lords in *In re Findlay* [1985] AC 318. It is only a failure to take into account the latter which may render a decision *ultra vires*.
76. Here the evidence of Ms Raine was that Lord Hunt was not provided with a copy of Professor Ernst's Review, but did have the advice of the CSM and the Medicines Commission, together with an explanation of the current status of the adverse reaction reports (as already described by Sedley LJ) and, as to Professors Ernst's work, the following:

“an explanation that Professor Ernst, a member of the Medicines Commission, opposed the prohibition and had contributed to the lengthy discussion at the Commission's meeting, but that ultimately the Commission had reached the view that an Order was justified. Professor Ernst's objections to the prohibition of kava-kava were summarised.”

The minister may not have been aware of Professor Ernst's precise reputation and research studies, but he did know that the professor was a member of the Medicines Commission, with the expertise which that implied, and the minister had a summary of the professor's objections to a ban. In those circumstances, I cannot accept that those matters of which the minister was unaware were of such significance as to render invalid the decision which he reached. For these reasons as well as those set out by Sedley LJ, I would dismiss this appeal.

Mr. Justice Bennett:

77. I agree and only wish to add some observations on the issue whether Lord Hunt left relevant matter out of account in deciding to make the Order. The submission of Mr Thompson Q.C., for the appellants, is that Lord Hunt made his decision re the Order in ignorance of “a material point of fact” (to quote paragraph 2 of his supplementary

skeleton argument) which he should have taken into account. In particular, Professor Edzard Ernst had just completed a controlled meta-analysis of all the randomised, double-blind, placebo-controlled trials available on the issue of safety and efficacy of kava-kava, conducted in accordance with the rigorous standards of a Cochrane Review. This analysis was thus the most objective and reliable source of scientific evidence currently available. Lord Hunt was neither told of Professor Ernst's special expertise in this field, nor that he had just completed the highest level review of the available scientific evidence, nor of the conclusions of the review.

78. Crane J. summarised the appellants' submissions at paragraph 20 of his judgment:-

"the Commission and/or the civil servants failed to inform... Lord Hunt that (a) a recent, highly authoritative report had been prepared by one of the leading experts, Professor Edzard Ernst, (b) Professor Ernst had presented the findings of the report at the meeting on 7 November 2002 at which the Commission reached the conclusions submitted to the First Defendant, (c) the reports findings were wholly inconsistent with the advice that was given to the First Defendant on the basis of admittedly incomplete and unsatisfactory data on rare adverse effect reports."

79. Crane J. reviewed the history and the evidence between paragraphs 21 and 65 inclusive of his judgment. The nub of his judgment on this point is to be found at paragraph 81, where he said:-

"The complaint is in essence that Lord Hunt was not informed about Professor Ernst's 2002 Review or the extent of his opposition to the proposal. However, the evidence indicates that this Review and his opposition were considered by responsible civil servants. Although Lord Hunt was not provided with the Review, he was told of Professor Ernst's opposition and provided with a summary of the Professor's objections. It is not submitted that Lord Hunt should have read the Review, only that he should have been aware of its existence. In my judgment what was provided for him was both adequate and appropriate."

80. The question is whether Crane J. could properly come to the conclusion he did, in particular with reference to the last sentence of paragraph 81 of his judgment.

81. There is, as I understand it, no dispute that, as a matter of law, the ground of failure to take into account a relevant consideration can only be made out if a decision-maker fails to take into account a consideration which he is bound to take into account in making that decision, Associated Provincial Picture Houses Ltd v Wednesbury Corporation [1948] 1 KB 223, Minister for Aboriginal Affairs and another v Peko-Wallsend Limited and others (1986) 162 CLR 24, 39. Further, what factors a decision-maker is bound to consider in making the decision is determined by the construction of the statute conferring the discretion. If the discretion is unconfined by the terms of the statute, the court will not find the decision-maker is bound to take a

particular matter into account unless an implication that he is bound to do so is to be found in the subject-matter, scope and purpose of the Act, Peko-Wallsend page 40.

82. The statutory provisions are to be found in the Medicines Act 1968. Sedley L.J. has summarised the relevant provisions at paragraphs 11 and 12 of his judgment.

83. Mr Cavanagh Q.C., for the First Respondent, submitted that in the circumstances of this case it was not necessary for Lord Hunt to have been told of the matters set out in the third bullet point of paragraph 12 of Dr Raine's statement of 5 November 2003. It would have been sufficient for the Minister to have been given the advice from the CSM or the Medicines Commission (as required by the 1968 Act) and not the views of a dissentient, however eminent. "Advice" from different experts has to be evaluated and synthesised by the Commission in the expectation that a unified advice will be able to be given to the Minister. As Dr Raine said (paragraph 4 of her statement of 6 October 2003):-

"... his [i.e. Professor Ernst] views were in a very small minority. I should add that the lack of unanimity amongst the members of the Commission is by no means unknown, but the practise of the Commission, in line with its statutory role, is to give a single, unified statement of advice to the Secretary of State, rather than to present a range of conflicting views."

84. Mr Cavanagh's submission must have limits. One can envisage a situation where the members of the Commission might polarise into two or three camps, each expressing wholly contrary or inconsistent viewpoints. In such a situation it would be difficult, if not impossible, for the advice given by the Commission to be expressed in a "unified statement of advice". The "advice" would have to reflect the different viewpoints; otherwise to present to the Minister the advice of one camp as the advice of the Commission would present a false picture.

85. However, although I am attracted by Mr Cavanagh's submission, I do not think it would be right to decide the point in issue on that ground. For the case has been argued fundamentally on the basis that the information provided Lord Hunt was sufficient, and that was the basis upon which the judge proceeded.

86. Mr Thompson drew our attention to what he submitted were the core conclusions of Professor Ernst's analysis, namely:-

- the reviewed data suggest that kava is safe for short-term treatment
- adverse events reported in reviewed trials were mild, transient and infrequent
- No plausible mechanism for the alleged hepatotoxic effects of kava has so far been identified. The question therefore remains whether the frequency of liver damage in kava users differs significantly from that of non-kava users.

- as to efficacy, the core conclusion from the data received was that kava-kava “is superior to placebo as a symptomatic treatment of anxiety.”

87. Mr Thompson submitted that Lord Hunt was unaware of the status of Professor Ernst as the Commission’s principal expert on the issue of complementary medicines and kava-kava in particular, and of the existence of his very recently completed Cochrane Review which found good evidence of efficacy and poor evidence of its harmfulness. He further submitted that this was a serious procedural flaw in the decision-making process.
88. In deciding what Lord Hunt was bound to consider Mr Cavanagh drew our attention to certain passages in the judgments of the High Court of Australia in Peko-Wallsend. Gibbs C.J. agreed with the reasons given by Mason J. and added at pages 30 and 31:-

“Of course the Minister cannot be expected to read for himself all the relevant papers that relate to the matter. It would not be unreasonable for him to rely on a summary of the relevant facts furnished by the officers of his Department. No complaint could be made if the departmental officers, in their summary, omitted to mention a fact which was insignificant or insubstantial. But if the Minister relies entirely on a departmental summary which fails to bring to his attention a material fact which he is bound to consider, and which cannot be dismissed as insignificant or insubstantial, the consequence will be that he will have failed to take that material fact into account and will not have formed his satisfaction in accordance with law.”

Mason J. said at page 45:-

“It would be a strange result indeed to hold that the Minister is entitled to ignore material of which he has actual or constructive knowledge and which may have a direct bearing on the justice of making the land grant, and to proceed instead on the basis of material that may be incomplete, inaccurate or misleading. In one sense this conclusion may be seen as an application of the general principle that an administrative decision-maker is required to make his decision on the basis of material available to him at the time the decision is made. But that principle is itself a reflection of the fact that there may be found in the subject-matter, scope and purpose of nearly every statute conferring power to make an administrative decision an implication that the decision is to be made on the basis of the most current material available to the decision-maker.”

Brennan J. said at page 61:-

“A decision-maker who is bound to have regard to a particular matter is not bound to bring to mind all the minutiae within his knowledge relating to the matter. The facts to be brought to mind are the salient facts which give shape and substance to the matter: the facts of such importance that, if they are not considered, it could not be said that the matter has been properly considered.”

89. Mr Cavanagh drew our attention to other passages in Professor Ernst’s analysis which went more directly to the issue of the safety of kava-kava, Under “Synopsis” the last sentence reads:-

“Further and more rigorous investigations into the effectiveness and safety of kava extract would be welcome.”

Under “Reviewers’ conclusions”, it said, after stating that the reviewed data suggested that kava was safe for the short-term treatment,:-

“Given the recent reports of adverse events, kava should not be taken concomitantly with hepatotoxic drugs or over long periods of time. Further rigorous investigations, particularly into the safety profile of kava are required.”

That last sentence was repeated on page (internal) 11 of the analysis.

90. Thus, in my judgment, it cannot be said that Professor Ernst’s analysis established that kava-kava was safe. At the very least his analysis suggested that further, rigorous investigations were required “particularly into [its] safety profile...”

91. The Medicines Commission’s advice stated, inter alia:-

- “The exact mechanism for the hepatotoxicity associated with kava-kava had not been identified to date, although a clear link was established between the use of kava-kava and the occurrence of hepatotoxic reactions...”
- “The Medicines Commission concluded that there was evidence of a risk, in rare cases, of hepatotoxicity associated with... kava-kava, which may be severe. The hepatotoxic effect of kava-kava is unpredictable, and no specific factors relating to an increased risk with specific preparations, doses or groups of susceptible patients could be identified. The Medicines Commission considered that the prohibition of kava-kava in unlicensed medicines was the appropriate regulatory action on the basis of the evidence available.”

92. Dr Raine has stated (paragraph 12 of her statement of 5 November 2003) that the submissions to Lord Hunt included the advice from the Committee of the Medicines

Commission and an explanation of the current status of the adverse reaction reports. Further Lord Hunt was told:-

- (i) that Professor Ernst, a member of the Commission, had opposed the prohibition,
- (ii) that he had contributed to the lengthy discussion at the Commission's meeting,
- (iii) that ultimately the Commission had reached the view that an order (i.e. of prohibition) was justified, and
- (iv) of Professor Ernst's objections to the prohibition. They were summarised and, I infer, for the benefit of the Minister.

She also stated that neither a copy of the Review (of Professor Ernst) nor any other primary scientific materials (I infer, from experts other than Professor Ernst) were provided to Lord Hunt.

- 93. I accept Mr Cavanagh's submission that Professor Ernst's analysis or review was one piece in the evidential jigsaw relating to the safety of kava-kava. Professor Ernst's conclusions were not unqualified and did not override the other evidence. Furthermore the Minister was made aware of his objections to the prohibition and that he had contributed to the lengthy deliberations of the Commission. Thus the Minister had the opportunity to make further enquiries in relation to Professor Ernst's objections and to ask for further details. He was not denied the knowledge that Professor Ernst, a member of the Medicines Commission, had objected. Nor was the Minister put in the position of being given the primary scientific materials except that of Professor Ernst.
- 94. Thus I conclude that Crane J. was, with respect, right in his analysis. The facts brought to the attention of Lord Hunt were, to adopt the words of Brennan J. in Peko-Wallsend, "the salient facts which give shape and substance to the matter". They were not "incomplete, inaccurate or misleading" per Mason J.
- 95. For these reasons as well as those set out by Sedley and Keene LJ I would dismiss this appeal.

ORDER: Appeal dismissed.

(order does not form part of approved judgment)